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Part 219 Alcohol/Drug Program Compliance Manual

For The Railroad Industry

FEDERAL RAILROAD ADMINISTRATION

Office of Safety

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This Federal Railroad Administration (FRA) Part 219 Alcohol/Drug Program Compliance Manual was developed for FRA by GREYSTONE HEALTH SCIENCES CORPORATION under DTFR53-96-C-00007. The author of this document for FRA's Office of Safety was George M. Ellis, Jr.

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1.0

INTRODUCTION

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1.0 INTRODUCTION AND PURPOSE OF THE MANUAL

1.1 INTRODUCTION

Drug and alcohol abuse among Federally regulated transportation workers has triggered significant concern about public safety, environmental protection, and economic impact at the local, state, and national levels. The Department of Transportation (DOT) has made a strong commitment to assist regulated employers with this problem, believing it essential to commercial transportation safety and protection of the American public. In late 1988, the Department of Transportation and its various operating administrations enacted aggressive regulations to help employers eliminate the use of drugs and the abuse of alcohol in regulated transportation industries and to facilitate a safe, drug and alcohol-free workplace.

Federal Railroad Administration (FRA) regulations in 49 CFR Part 219 (as amended) establish minimum Federal safety requirements for the control of alcohol and drug use in railroad operations. The regulations are designed to assist carriers in preventing accidents and casualties by implementing comprehensive drug and alcohol detection and deterrence programs.

Ultimately, Part 219 is intended to be a human factors regulation which reduces both the economic cost to railroad operations and the loss of personnel because of the use of drugs and the misuse of alcohol. To properly comply with its intricacies, carriers must be prepared to devote quality personnel and apply sufficient operational resources to make this essential safety program successful. FRA holds carriers fully accountable and responsible for the proper performance of its program, its program personnel, and its service providers.

1.2 PURPOSE OF THE PART 219 COMPLIANCE MANUAL

Implemented more than a decade ago and amended periodically since, Part 219 is a comprehensive and far-reaching safety regulation. Even with its numerous successes and achievements, however, Part 219 has sometimes proven difficult to properly implement. Its elements, like the problem it hopes to eliminate, are complex and do not always lend themselves to simple compliance strategies. As a consequence, both rail carriers and FRA working in a partnership have

sometimes struggled to establish a common ground on the proper implementation of some of the regulation's subparts.

Formal audits of carrier compliance with Part 219 provisions can be extremely difficult for both the railroad and FRA. Carrier record systems are often inadequate and documentation of program performance can fall well short of FRA standards. Inadequate carrier record systems are considered non-compliant by FRA.

The purpose of this Compliance Manual is to eliminate some of the complexity and confusion of proper program compliance by providing carriers and FRA Safety Inspectors with an indepth description of exactly what FRA expects in a successful Part 219 drug and alcohol program. For each required program element, FRA has outlined its program goals and offered a summary of what it wants to see when it evaluates a carrier's Part 219 performance. With FRA's expectations more clearly defined, carriers can also better audit themselves and develop a drug and alcohol program which more fully meets FRA standards.

1.3 MANUAL UPDATES

FRA intends that this Manual will be periodically updated as significant program changes occur, usually no more often than once per year. The latest updated version of the Manual or any of its various sections may be determined by contacting the FRA Alcohol and Drug Program Manager.

2.0

APPLICABILITY,

DEFINITIONS,

REGULATORY AUTHORITY,

AND

ENFORCEMENT PHILOSOPHY

2.0 Applicability, Definitions, Regulatory Authority, and Enforcement Philosophy

2.1 APPLICABILITY

All railroads affected by FRA's regulation on the control of alcohol and drug use in regulated operations (49 CFR Part 219) must adhere to the requirements described below.

All railroads which have sixteen (16) or more covered service employees, or who have joint operations with another railroad, must abide by the requirements found in the general section (Subpart A); the prohibitions (Subpart B); mandatory post-accident testing (Subpart C); testing for cause (Subpart D); the identification of troubled employees (Subpart E); pre-employment testing (Subpart F); random testing (Subpart G); procedures and safeguards for urine drug testing and for alcohol testing (Subpart H); and recordkeeping requirements (Subpart J).

All railroads which have fifteen (15) or less covered service employees need only observe the general section (Subpart A); the prohibitions (Subpart B); mandatory post-accident testing (Subpart C); procedures and safeguards for urine drug testing and for alcohol testing (Subpart H) when applicable; and recordkeeping requirements (Subpart J) when applicable. They are exempt from Federal testing for cause, programs for the identification of troubled employees, pre-employment testing, and random testing.

Regardless of size, carriers are not limited by FRA regulations from conducting any type or kind of drug or alcohol testing, or implementing drug and alcohol programs for their employees, under their own authority. FRA has no interest in company authority programs except as the lines of distinction appear to be blurred with Federal requirements (i.e. use of a Federal collection form).

Carriers must submit an annual report covering their alcohol and drug use programs (Subpart I), if they have 400,000 or more total manhours in the calendar year.

When operating in U.S. territory with covered service employees whose primary place of service ("home terminal") is outside the U.S., foreign carriers must conform with FRA requirements for the general section (Subpart A), the prohibitions (Subpart B), mandatory post-accident testing (Subpart C), and testing for cause (Subpart D). These operations are exempt from the FRA requirements for programs for troubled employees, pre-employment testing, and random testing.

2.2 DEFINITIONS

For purposes of 49 CFR Part 219 and this Compliance Manual, the following operational definitions apply:

Covered Employee. A covered employee is defined as a person who either performs service during a duty tour or is assigned to perform service under the Hours of Service laws. That person may be an employee, contractor, or volunteer. An applicant for a position which has covered service responsibilities is considered a covered employee for all applicable purposes in Part 219. In general, train and engine service employees (including some hostlers), dispatching service employees, and signal employees may be subject to Part 219 regulations.

Railroad. A railroad affected by Part 219 must be operating on a standard gage track which is part of the general railroad system of transportation. This affects both freight and passenger operations, and certain commuter and other short-haul passenger service. Part 219 does not affect a railroad which only operates on tracks inside an installation and/or not part of the general transportation system (plant railroads and rapid transit operations within an urban area).

2.3 EFFECT OF HOURS OF SERVICE LAWS

The Hours of Service laws apply to Part 219 employee testing programs as follows:

For random testing, the collection must be completed within the employee's Hours of Service duty period. If Hours of Service expires (including during a shy bladder situation), the employee must be released immediately from his or her testing obligation without sanction and the employer may not later recall the employee to complete the collection or place them in a special selection testing pool.

Because they are unpredictable tests, a carrier may require an employee to exceed their Hours of Service if the testing is for mandatory post-accident, reasonable suspicion, or Federal reasonable cause. FRA also permits exceeding Hours of Service if reasonable cause testing is being conducted under the company's own authority but the thresholds which could trigger a Federal reasonable cause test have been met. In all of these cases, the railroad must report the Hours of Service for the employee. However, FRA will use its prosecutorial discretion and not file a violation if the carrier used due diligence to immediately complete the collection.

For Federal follow-up testing, Hours of Service laws apply to the normal collection process and the carrier is permitted to reschedule if the collection must be terminated. However, the carrier can require the employee to exceed Hours of Service if the collection turns into a shy bladder situation before the employee's Hours of Service expires. Like in the paragraph above, the carrier must report the employee's excess service but the FRA will not apply a sanction if the carrier demonstrates due diligence in completing the collection.

In certain circumstances, an employee may be called on duty for purposes of having a specimen collected (i.e., a follow-up test when the employer is having difficulty obtaining a specimen because of the employee's unpredictable schedule, or a random test for those employees that are on an emergency call list or are first out on an extraboard, etc.) In such circumstances, normal Hours of Service laws apply for purposes of obtaining specimens.

2.4 REGULATORY AUTHORITY

Regulations which establish Federal requirements for rail carriers conducting drug and alcohol testing under FRA authority can be found at 49 CFR Part 219. Department of Transportation Office of the Secretary (DOT) regulations which support FRA testing can be found at 49 CFR Part 40. FRA regulations establish when testing is required and can be conducted, who is to be tested, and the actions which must be taken when an applicant or employee passes or fails a required test. DOT regulations provide the technical/scientific/medical detail on how FRA drug and alcohol specimens are to be collected, analyzed, reviewed, and reported.

Carriers are reminded that in their consideration of any FRA drug and alcohol issue, they must rely on the following sources of information (in priority order):

- 49 CFR Part 219, as amended
- 49 CFR Part 40, as amended
- Published FRA guidance, including this Compliance Manual
- Published DOT guidance
- Written FRA rule interpretations
- Written DOT rule interpretations
- Verbal guidance from the FRA Alcohol and Drug Program Manager
- Verbal guidance from DOT's Drug and Alcohol Policy and Compliance Office
- Verbal guidance from FRA Regional Drug and Alcohol Specialists

Carriers should not rely solely on verbal guidance when taking a significant Part 219 program action, and should instead obtain written affirmation from FRA or DOT as a followup.

Information, rule interpretations, and program guidance provided by third parties including railroad organizations, trade or vendor associations, and unions do not hold any weight with FRA in determining carrier compliance with Part 219 or Part 40. Whenever possible, the carrier should not undertake a significant course of action under Part 219 without written Federal authority or reference.

2.5 49 CFR PART 219

49 CFR Part 219, "Control of Alcohol and Drug Use", has been FRA's cornerstone drug and alcohol regulation since 1985. It establishes the purpose and scope of FRA's drug and alcohol program requirements, and provides Federal standards for control of drug and alcohol use on regulated railroads. The regulation is broken down into ten subparts. They are:

- Subpart A —General. Subpart A establishes the general application, purpose and scope of Part 219. It provides program definitions; identifies the conditions for waivers; establishes responsibility for compliance; and describes general conditions for chemical tests. It also contains important information required of railroads in their drug and alcohol policies and procedures.

Regulatory Authority

- Subpart B — Prohibitions. Subpart B contains the basic prohibitions regarding on and off-duty drug and alcohol use; describes the use of prescribed and over-the-counter drugs; establishes the carrier's responsibility for action if an applicant or employee violates the prohibitions; establishes the carrier's responsibility for due diligence in preventing violations of Part 219; and describes the consequences for applicants and employees if they refuse a required test.

- Subpart C —Post-Accident Toxicological Testing. Subpart C establishes the rule-triggering events for which mandatory post-accident testing is required and the thresholds which initiate testing; identifies the covered employees and others who are to be tested after each event; establishes the responsibilities of both the carrier and its employees; describes sample collection and specimen handling for both surviving employees and fatalities; describes the reporting required; and identifies the consequences of refusing this required test.

- Subpart D — Testing for Cause. Subpart D establishes the requirements for mandatory reasonable suspicion testing and the authorization for Federal reasonable cause testing. It also establishes the importance of prompt sample collections for alcohol and drugs and the procedures for each.

- Subpart E — Identification of Troubled Employees. Subpart E contains the carrier's requirements for establishing policies which facilitate the identification, and if applicable, the mechanism for return to duty for covered employees who abuse drugs and alcohol. Included are FRA's standards for a voluntary referral policy and a co-worker report policy.

- Subpart F — Pre-Employment Tests. Subpart F establishes the requirements for pre-employment testing of personnel who are being hired into or being transferred for the first time into covered service. Also included are the consequences of refusing a Federal pre-employment test.

- Subpart G — Random Alcohol and Drug Testing Programs. Subpart G contains the requirements for random testing including the submission requisites and FRA approvals necessary for the carrier's Random Plan; describes the yearly establishment by FRA of the drug and alcohol testing rates; and details random program implementation procedures.

- Subpart H — Procedures and Safeguards for Urine Drug Testing and Alcohol Testing. Subpart H contains some of the standards for drug and alcohol testing required by the rule but not found in other subparts, including drug testing procedures, the role of the Medical Review Officer (MRO), employee requests for split specimen testing, confidentiality required of the laboratory and of the MRO, and alcohol testing procedures.

- Subpart I — Annual Report. Subpart I contains guidelines on the information required from each carrier in its annual Management Information System (MIS) submission to FRA.

- Subpart J — Recordkeeping Requirements. Subpart J establishes the carrier's recordkeeping and access requirements for drug and alcohol testing records.

The rule also contains several appendices. Appendix A to Part 219 contains a listing of the civil penalties for carriers and employees who fail to comply with these regulations. Appendix B contains the name of FRA's designated mandatory post-accident laboratory. Appendix C establishes mandatory post-accident sample collection procedures. Appendix D (D1-D3) contains the MIS report formats.

2.6 49 CFR PART 40

49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs", establishes standards and procedures in the collection, laboratory analysis, medical review, and reporting of urine drug tests; and the collection, analysis, and reporting of breath alcohol tests being conducted under Department of Transportation (DOT) operating administration regulations. The regulations are broken down into four subparts. They are:

- Subpart A — General. Subpart A provides Part 40 applicability and definitions.

- Subpart B — Drug Testing. Subpart B establishes standards for the collection, testing, medical review, and reporting of urine tests. It also identifies standards for the protection of employee records and the qualification of testing laboratories.

- Subpart C — Alcohol Testing. Subpart C establishes standards for the collection of evidential-level breath alcohol specimens; the qualification of the testing devices; the qualification of collectors; the screening and confirmation testing of specimens; the calibration and maintenance of evidential-level breath testing devices; and procedures for refusals, uncompleted tests, and invalid tests. Limitations on the availability and disclosure of alcohol testing information is also discussed.

- Subpart D — Non-Evidential Alcohol Screening Tests. Subpart D establishes standards for the use of non-evidential breath and saliva alcohol screening devices.

The rule contains two appendices. Appendix A to Part 40 is a facsimile of the Federal Drug Testing Custody and Control Form (DTCCF). Appendix B is a facsimile of the Federal Breath Alcohol Test Form.

At the time of the first publication of the Compliance Manual in Fall 1999, DOT was completing a major rewrite and reorganization of Part 40. This rewrite is expected to materially affect portions of this Compliance Manual.

2.7 OTHER IMPORTANT DOCUMENTS

The carrier may wish to obtain copies of other important reference documents, including the DOT's Urine Specimen Collection Procedures Guidelines (December 1994), the Medical Review Officer Guide (October 1990), and the Substance Abuse Professional Procedures Guidelines (June 1995). All of these documents are currently in revision themselves or are likely affected by the current revision of 49 CFR Part 40 due out in Summer 2000. It is therefore recommended, that except where noted in the text of this Compliance Manual, carriers may wish to rely on the Rules themselves or the guidance provided in this document.

3.0

PROHIBITIONS

3.0 PROHIBITIONS

3.1 OVERVIEW

FRA regulations found in 49 CFR 219.101 – 219.107 (Subpart B) describe FRA drug and alcohol use prohibitions governing railroad employers and their employees, contractors, and volunteers who perform covered service. FRA's intent is that all covered service personnel are aware of FRA prohibitions and the consequences of violating FRA's drug and alcohol rules. FRA's goal is that the carrier exercises due diligence in preventing violations of these prohibitions to the degree possible. FRA prohibitions must be clearly disseminated to all covered service personnel, and the carrier must ensure that all applicable railroad policies, procedures, and practices are consistent with these prohibitions.

3.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Alcohol; Alcohol Concentration (or Content); Alcohol Use; Controlled Substance; Covered Employee; Drug; Possess; Refuse to Submit
- 219.23 – Railroad Policies
- 219.101 – Alcohol and Drug Use Prohibited
- 219.102 – Prohibition on Abuse of Controlled Substances
- 219.103 – Prescribed and Over-the-Counter Drugs
- 219.104 – Responsive Action
- 219.105 – Railroad's Duty to Prevent Violations
- 219.106 – [Reserved]
- 219.107 – Consequences of Unlawful Refusal

3.3 INSPECTION GOAL

The goal for inspecting this element is to determine whether the carrier fully supports and is properly disseminating information on FRA drug and alcohol prohibitions to all covered service personnel. It is essential that the carrier ensure that all of its applicable practices and procedures to train, implement, and enforce these prohibitions are consistent with the regulations, and that covered personnel found to be in violation of 219.101 or 219.102 are removed from service expeditiously and handled in strict accordance with FRA requirements.

3.4 RECORDS REQUIRED

The inspector should review all carrier drug and alcohol policies, procedures, and distributed materials to ensure that FRA prohibitions are clearly described and distinguished from applicable company policies and Rule G. The inspector should assess carrier records to determine whether the required dissemination of information to employees on the drug and alcohol prohibitions has been accomplished, and audit the content of the materials provided. The inspector should also evaluate individual verified positive cases to determine if positive personnel are being relieved without unnecessary delay from covered service and that they are not being returned before they meet the full requirements of the Rule. Interviews with employees and supervisors throughout the carrier's system should be conducted.

3.5 PROHIBITIONS

3.5.1 ***Determine that all applicable carrier drug and alcohol policies, procedures, training, and other written or posted materials for covered service employees are adequately disseminated and clearly describe FRA prohibitions identified in 219.101 and 219.102.***

3.5.2 ***Determine that all applicable carrier practices for covered service employees, whether formal or informal, clearly support FRA prohibitions described in 219.101 and 219.102, and are clearly distinguishable from the carrier's company policy and/or Rule G if they are different.***

All carrier policies, procedures, other related documents and practices must clearly distinguish between Federal drug and alcohol prohibitions and carrier policy if they are different. The carrier's Rule G should at the least support and enhance FRA prohibitions, but if it goes beyond FRA requirements it must also be clearly distinguished from FRA regulations.

All covered service personnel must be generally knowledgeable of FRA prohibitions, which they should have received from carrier training, from formal or informal interaction with supervisors, from carrier practices, and/or from published materials made available to them to fulfill the requirements of 219.23. The carrier should be prepared to document any formal efforts to educate covered employees on FRA prohibitions and testing requirements.

PROHIBITIONS

In 219.101, covered service personnel (employees, contractors, volunteers) are prohibited from possessing, being impaired by, or working under the influence of a controlled substance while on duty or subject to duty. In addition, covered personnel are also in violation of 219.101 if they are under the influence or impaired by alcohol; have a blood alcohol concentration (BAC) equivalent to 0.04% or greater; or have ingested alcohol within four hours of reporting for duty or after receiving notice to report for covered service (whichever is the lesser period).

If the BAC result is 0.02% - 0.039%, covered personnel must be removed from covered service until their next regularly scheduled duty tour, but not less than eight hours. They need not be evaluated by a SAP, nor are they required to comply with any other FRA requirements before returning to duty. This is considered a credible positive result, but not a violation of 219.101. The regulation therefore allows the carrier to take administrative action under its own authority.

Breath alcohol concentrations of less than 0.02% from a Federal collection are negative tests. The carrier is not permitted to take any administrative action on a Federal result of greater than 0.00% and less than 0.02%, nor may they use this finding as the nexus for conducting their own alcohol test under company authority.

Additional company policy testing after a negative Federal test (below 0.02%) would only be permitted in the extraordinarily rare circumstance where following a reasonable suspicion, Federal reasonable cause, or Federal follow-up test, the carrier's trained supervisor was present and made an independent post-test reasonable suspicion determination based on the covered employee's body odors, speech, behavior, or appearance. However, this same allowance would not be permitted following a Federal random test. Carriers are not permitted to use this special circumstance as an opportunity to achieve a different test result, and any such case should be thoroughly investigated by FRA. Unless there is compelling evidence to support the need for additional testing, FRA will likely consider administrative action against the carrier.

In 219.102, covered service personnel are prohibited from using a controlled substance at any time, on or off duty, unless it is authorized or prescribed by a medical practitioner and has been determined not to affect the safe performance of the person's covered duties. This FRA prohibition may differ from the traditional carrier Rule G, which sometimes does not prohibit non-medical use of a controlled substance while off-duty.

In most circumstances, absent other credible evidence which specifically supports a finding of impairment or under the influence, a urine test positive for drugs will usually only be chargeable under 219.102. By the nature of the sample type itself, a urine positive will not ordinarily reveal the amount or recency of the drug used.

In both 219.101 and 219.102, covered personnel in violation of these prohibitions may not be returned to covered service until they meet the requirements of the Substance Abuse Professional (SAP) and are fully qualified for duty under FRA regulations.

In both 219.101 and 219.102, FRA does not address the issue of employment. Carriers may choose to retain or not retain an individual with a verified positive drug test or BAC concentration at or above 0.02%, but the decision must be made in accordance with their own company policy or collective bargaining agreement.

FRA expects that the carrier should also be interested in the use of other potentially impairing medications, whether prescribed or over-the-counter, even if they are not controlled substances (this issue will be discussed in more detail in Section 3.5.3 and 3.5.4).

3.5.3 *Determine that the carrier fully supports and enforces a policy that ensures compliance with 219.103.*

To perform covered service, personnel may use one or more controlled substances when prescribed or authorized by a physician if a medical determination is made that use of the medication(s) will not adversely impact the safe performance of their duties. The medications must be used at the dose prescribed or authorized by the physician. If more than one controlled substance is being used, a single physician with a complete knowledge of all the medications being taken and the employee's duties must make this medical judgment. The determining physician may be either the employee's doctor or a doctor selected by the employer. FRA's intent is that the responsibility for this requirement rests with the employee, but it is the employer's responsibility to ensure that employee is made aware of the regulation.

The railroad is also not restricted from establishing its own separate notification requirement for any therapeutic drug use, including compelling covered personnel to obtain prior approval from the carrier for such use (usually through the carrier's medical department).

Although not required by the regulations, FRA encourages carriers to remain vigilant about the use of other potentially impairing prescribed and over-the-counter medications by employees that are not controlled substances (that is, do not have dependence potential). Such a special interest by the carrier would be consistent with an interest in rail safety and demonstrate the carrier's support of FRA safety regulations.

3.5.4 ***Determine whether the carrier takes immediate action in relieving covered personnel in violation of 219.101 or 219.102 from duty, whether the employee receives the proper notice and opportunity for a hearing in a timely manner, whether the employee is not returned to covered service until all requirements of the rule are met, and whether the employee receives sufficient follow-up tests once back on covered duty.***

3.5.5 ***Determine whether the carrier takes the same immediate action with covered service personnel who are detected adulterating or substituting their urine sample, or have refused a required drug or alcohol test.***

Once a covered employee is determined to be in violation of 219.101 or 219.102 (or having refused a required drug or alcohol test), the carrier is responsible for immediately removing that individual from covered service as soon as it is practical. Personnel so identified must be notified of the reason for their removal from covered service and must be given the opportunity for a hearing within the timeframe specified in the collective bargaining agreement, or absent an agreement, within 10 days of the MRO's final report. A refusal requires a minimum nine month suspension from covered service.

Once removed, no consideration may be given to returning someone to covered duties until the SAP has recommended consideration of that individual for return to covered service. The carrier must also ensure that a Federal return-to-work test is on file before the employee is allowed to return (drug, alcohol, or both as determined by the SAP), and that SAP-recommended Federal follow-up tests are all being conducted. Federal return-to-work and follow-up tests must also be performed for covered personnel who were found to be in possession of a controlled substance in violation of 219.101.

3.5.6 ***Determine that the carrier has exercised due diligence in ensuring its employees comply with 219.101 and 219.102, and does not permit an employee to either go on covered duty or remain on duty when it has actual knowledge that the employee has violated 219.101 or 219.102.***

A carrier may not allow personnel to perform covered service if a railroad management employee has knowledge that the individual is in violation of 219.101 or 219.102. This knowledge must be based on direct information (not just from a third party), and be of sufficient credibility that the management employee may reasonably believe that 219.101 or 219.102 has been violated.

The carrier must make every effort to ensure that its covered personnel are complying with 219.101 and 219.102 and may not overlook potential violations through its own negligent actions (or failure to act). The carrier has a responsibility to continually improve its ability to detect and deter covered service personnel from misusing drugs or alcohol in violation of FRA regulations. The railroad's practices may not offer an opportunity for covered personnel to avoid detection because of carrier carelessness, indifference, or inattentive performance.

In deciding whether they must take action based on an allegation, employers must make a good faith determination based on the available relevant evidence at hand. The decision should be made by a knowledgeable and authorized management official after reasonable inquiry into the facts of the case that are available at that time. No adverse action should ever be taken without specific evidence of a violation. Guesses, suppositions, or conjectures do not constitute evidence. Signed affidavits from credible, reputable witnesses may.

Prohibitions Summary Checklist

I. Prohibitions [3.5]

A. *Determine that all applicable carrier drug and alcohol policies, procedures, training, and other written or posted materials for covered service employees are adequately disseminated and clearly describe FRA prohibitions identified in 219.101 and 219.102.* [3.5.1]

B. *Determine that all applicable carrier practices for covered service employees clearly support FRA prohibitions described in 219.101 and 219.102, and are clearly distinguishable from the carrier's company policy and/or Rule G if they are different.* [3.5.2]

C. *Determine that the carrier fully supports and enforces a policy that ensures compliance with 219.103.* [3.5.3]

D. *Determine whether the carrier takes immediate action in relieving covered personnel in violation of 219.101 or 219.102 from duty, whether the employee receives the proper notice and opportunity for a hearing in a timely manner, whether the employee is not returned to covered service until all requirements of the rule are met, and whether the employee receives sufficient follow-up tests once back on duty.* [3.5.4]

E. *Determine whether the carrier takes the same immediate action with covered service personnel who are detected adulterating or substituting their urine sample, or have refused a required drug or alcohol test.* [3.5.5]

F. *Determine that the carrier has exercised due diligence in ensuring its employees comply with 219.101 and 219.102, and does not permit an employee to either go on covered duty or remain on duty when it has actual knowledge that the employee has violated 219.101 or 219.102.* [3.5.6]

4.0

SPECIMEN COLLECTION

URINE

4.0 SPECIMEN COLLECTION - URINE

4.1 OVERVIEW

Department of Transportation regulations found in 49 CFR 40.23 and 40.25 and FRA regulations found in 219.11 and 219.703 describe requirements for the collection of urine specimens under Part 219 for all but mandatory post-accident testing (Subpart C). Part 219.205 and Appendix C to Part 219 (with exhibits) contain urine collection instructions for Subpart C rule-triggering events. In this section, the principal focus will be on urine collections for all but mandatory post-accident testing, although many of the elements will apply equally.

FRA considers the carrier wholly responsible for the performance of its urine specimen collectors, including for mandatory post-accident testing. This is true even if collection services, collection sites, or individual collectors have been contracted for by an outside third party administrator or consortium.

The role of the urine specimen collector is to ensure that the samples obtained from the carrier's applicants or covered employees have been collected in a manner consistent with DOT and FRA regulations and guidelines. For each FRA collection, the collection site must have been properly prepared; the specimen obtained with Federal standards maintained and proper procedures followed; and the collection properly documented on a Federal collection form. The specimen arriving at the carrier's laboratory must give ample evidence that it was collected, labeled, and sealed in accordance with the Federal requirements and that there was no evidence that the sample itself had been compromised. There must be no evidence that the sample had been mixed up with another donor's or that the specimen arriving at the laboratory could have been contaminated or adulterated by someone other than the donor.

Collectors must be knowledgeable about all Federal collection requirements; be properly vigilant to detect attempts at diluting, substituting, or adulterating the sample by the donor; and be capable of properly handling refusals, shy bladder situations, or other unusual collection events in accordance with DOT and FRA regulations and guidance.

4.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 40.3 – Definitions: Cancelled or Invalid Test; Chain of Custody; Collection Container; Collection Site; Collection Site Person; Shipping Container; Specimen Bottle
- 40.23 – Preparation For Testing
- 40.25 – Specimen Collection Procedures
- 219.5 – Definitions: Refuse to Submit; Supervisory Employee
- 219.11 – General Conditions for Chemical Tests
- 219.703 – Drug Testing Procedures

4.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier employs urine collectors for Part 219 testing that are experienced and fully knowledgeable of the regulations; can properly manage Federal specimen collections, including site preparation, sample collection, and transfer of the specimen to the laboratory in accordance with applicable standards of practice; can capably perform difficult or complicated collections (shy bladder, refusals, adulteration attempts, etc.); and can collect samples in a professional manner, seeking a product which can achieve a scientifically sound and legally defensible laboratory test result.

4.4 RECORDS REQUIRED

The inspector should examine MRO test records (negatives, positives, and MRO downgrades) to ensure the completeness and accuracy of the documentation of collections. The inspector should interview one or more collectors performing this service for the carrier, and wherever possible, conduct a full mock collection with one or more selected collectors in the carrier's system.

4.5 PREPARATION FOR COLLECTIONS

4.5.1 *Determine that the collection location is suitable for a properly secure and confidential urine collection for drugs.*

FRA permits Part 219 urine collections at any reasonable location, including carrier property, as long as Part 40 requirements can be met. The collection location must be able to provide (at a minimum) an enclosure where privacy for urination is possible, a toilet or urinal to complete the void, a source of water for washing hands, and a suitable writing surface for annotating the specimen seals

and the Drug Test Custody and Control Form (DTCCF). The specimen (the void) must be provided in an area which is secured from the public, other employees, or other unauthorized individuals who may innocently or purposely interfere with the collection process.

The collection area (where the void will be provided) must not allow the donor access to used or unused collection materials (bottles, containers, forms, etc.); cleaning products, soaps, or other disinfectants; standing water or liquid of any kind that has not been specially marked with bluing; trash cans, etc. Faucets and other water sources in the collection area must be secured.

4.5.2 ***Determine that the collector has proper urine collection supplies, including Federal DTCCFs with tamper-evident seals, urine collection containers with temperature strips, split specimen transport bottles, and specimen shipment container(s).***

The collector should be fully prepared to collect specimens from the carrier's applicant or covered service employee. They should have sufficient supplies on hand to manage any reasonable eventuality if multiple collection kits or DTCCFs become required.

The DTCCF utilized should be for the laboratory contracted by the carrier. Although any approved Federal DTCCF may be used, even one for a different employer or for a different laboratory, modifying the Form to fit the carrier is neither preferred nor recommended. The unique identification number (UIN) on the Form and the UIN on the seals must match exactly. Under no circumstances can the collector or the laboratory modify the UIN regardless of the reasons.

The collector should also have access to a thermometer (other than rectal) to allow the donor to provide a body temperature if necessary (see Section 4.6.1).

4.5.3 ***Determine that the collector is properly qualified to conduct a Federal urine collection.***

The collector may be an employee of the carrier, a contractor, or be completely independent of the railroad. A supervisor in the donor's chain of command cannot be the collector.

The collector must be knowledgeable in Federal requirements for a proper urine collection and experienced in conducting Federal collections (either alone or

under supervision). The collector need not hold any special certification or training, but should be able to provide an inspector with documentation of training and experience, and demonstrate their expertise by answering inspector questions or participating in a mock collection. The collector does not need to demonstrate or document their abilities directly to the donor or the donor's agent.

As a reference tool, the collector should have direct access to written instructions which describe Federal collection requirements. In addition, it would be recommended that the collector have direct and/or immediate access to a supervisor or someone else who would be knowledgeable of Federal collection procedures.

4.6 FEDERAL DRUG COLLECTIONS

4.6.1 *Determine that the collector properly conducts a urine collection, correctly incorporating Federal procedures and standards.*

All of the collection procedures described below are important and should be performed in accordance with the regulation. The failure to follow these elements exactly, however, is not ordinarily fatal to the integrity and credibility of the collection unless otherwise noted.

The donor must first be properly identified through a picture ID, through direct identification by a supervisor, or other similar means. Verification of the donor's identity may not be by another worker, another donor, or through non-photo identification. Supervisor verifications may be by telephone as long as the identity of the donor is affirmed in sufficient detail.

The collector may only perform a collection with one donor at a time.

A properly completed copy of a DTCCF is found at Tab 1. The preliminary block on the DTCCF (Step 1) should be filled out before the donor provides the urine. All the other steps (Steps 2, 3, 4, 5, and 6) are to be filled out contemporarily to the individual collection actions themselves. Steps 2 – 6 are not to be filled out in advance of being performed, with the exception of the name, address, and telephone number of the collector/collection service in Step 5.

The donor's social security number or other ID number must be filled in the proper block (Step 1) or the laboratory will not test the specimen.

The donor should be asked to remove any outer garments as long as they don't intrude upon the donor's modesty. Purses, briefcases, backpacks, or other similar

bags may not be taken into the collection area. Only a wallet can be retained by the donor.

The donor may not be asked to empty pockets unless a suspicious bulge is noted. If a pocket is emptied, any material found which may be used to adulterate or contaminate a sample is to be retained outside the collection area. If it is the collector's reasonable belief that the donor could have attempted to alter their specimen with the material, the procedures necessary to conduct a direct observation collection should be initiated.

Any discovered material which could only have been used to adulterate or contaminate a specimen (i.e., another urine specimen, chemical product, etc.) should be confiscated and given to the employer. Any material which may be either innocent or not (i.e. Visine ®) can be returned to the donor at the end of the collection process. Failure of a donor to surrender suspicious material before or during the collection may be just cause to terminate the collection for failure to cooperate.

The donor should be asked to wash their hands before the collection, with the intent of removing any adulterants which may be present.

For urination, the collector should provide the donor with a wrapped/sealed collection container (with temperature strip) and/or a transport bottle. The wrapped container or bottle should be opened in the donor's presence. The donor can provide the specimen directly into either the specimen container or bottle. The specimen's temperature must be read within four minutes of the void to determine if it falls within the 90 to 100 degree Fahrenheit acceptable range. No temperature device may be placed directly into the urine to be sent to the laboratory.

All FRA testing requires a split specimen.

The donor must be afforded privacy for urination, unless a direct observation collection has been previously authorized. Donors may not be asked to disrobe, either wholly or partially, unless the urine collection is part of a legitimate scheduled medical examination required by FRA regulations.

The donor is ushered into a private area for urination, and the collector either is present just outside the door in a single toilet bathroom (considered a "private"

collection) or stands close by the stall in a secured public bathroom (considered a "monitored" collection). Whenever feasible, a private collection should be conducted.

When the void is provided, it is brought out to the collector. At least 45 mL is required (30 mL is minimum for the primary bottle and 15 mL is the minimum for the split).

The donor and the collector should proceed together to the area where the DTCCF is to be completed. The donor should be told not to wash their hands until the paperwork is complete and the specimen is sealed. The specimen may not leave the presence of the donor until the sealing is completed. Line-of-sight contact between the donor and the specimen is not required.

If the urine leaves the donor's presence without the donor's real or implied permission, the collection is seriously and perhaps fatally jeopardized. However, if it is the donor's choice not to be present, then the integrity of the collection is not challenged.

The temperature of any specimen received from the donor is to be recorded in Step 1 of the DTCCF. If the temperature of the specimen is between 90 to 100 degrees Fahrenheit, it should be accepted unless there is other evidence suggesting temperature tampering. If the temperature is either above or below the range, another specimen must be collected immediately under direct observation. This requirement can be waived if the donor agrees to have their body temperature taken and it is within two degrees Fahrenheit of the recorded specimen temperature.

If the second specimen is separately collected if required by regulation, both samples should be submitted to the laboratory with an explanatory annotation in the remarks section of the two DTCCFs. Refusal to cooperate in the second collection is considered a refusal to test.

The specimen is poured from the collection container into the two transport bottles and the bottles are sealed with the tamper-evident labels from the DTCCF. The label also contains the same specimen UIN found on the DTCCF. Without a label sealing the bottle, the laboratory will not test the specimen and the problem is not recoverable. The label is to be initialed and dated by the donor after it is on the bottle.

The rest of the DTCCF (Steps 4 – 6) is then to be filled out. The absence of the donor's signature or the collector's signature, or an improperly filled out transfer grid (Step 6), could cause the test to be cancelled by the laboratory or the Medical Review Officer (MRO) unless the problem can be remediated by a signed statement from the collector and/or donor. Other problems (i.e., too little specimen, no seal or UIN on the bottle, discrepant UINs between the bottle and Form, etc.) may not be recoverable and the test cancelled.

The collector must identify the specific type of courier used in Step 6 (i.e., FedEx, Airborne, UPS, laboratory courier, etc.), but the actual courier is not to sign the DTCCF.

The sealed specimen and appropriate copies of the DTCCF (Copies 1, 2, and 3) are to be placed in the plastic bag and sealed inside the shipping container. The shipping container itself should also be sealed. Copy 4 of the DTCCF (the MRO copy) is to be sent directly to the MRO. The other copies (copies 5, 6, and 7) are to be distributed as noted on the Form.

The donor may depart the collection area anytime after the specimen bottles are sealed. It is recommended, but not required, that they remain present through the sealing of the shipping container.

If the specimen is not to be shipped immediately, it should be held securely until the arrival of the courier service.

4.6.2 *Determine if the collector is able to distinguish between Federal and non-Federal collections.*

The collector may not employ a Federal form (the DTCCF) for a non-Federal test, and vice-versa. The collector may not use a portion of the Federal specimen for non-Federal testing (a company policy test or medical testing).

4.7 DIFFICULT COLLECTION PROBLEMS

4.7.1 *Determine that the collector is capable of handling a shy bladder collection.*

Current regulations allow a donor three hours to provide a specimen. DOT guidance requires the clock to start only after the donor's first attempt. The donor's verbal statement that they can't provide is insufficient to initiate shy bladder

procedures. The collector must ensure that the donor is physically in the collection area with collection materials readily available before it is permissible to be notified by the donor that they can't yet produce a specimen.

Every effort must be made to get the donor to provide an acceptable specimen. The collector must make fluid available, and permit the donor to drink up to 40 ounces of liquid. Although technically a collector is permitted to terminate a shy bladder collection because a donor was refusing to drink, this is never a recommended practice unless the donor is adamantly refusing to cooperate with the collection process. It is reasonable for the cooperative donor to argue that they should have the opportunity to choose when and if they drink, and it is not an issue of failing to cooperate. Regular reminders that the donor must drink, however, are important.

Although the donor may be required to return to work during the waiting period, it is not recommended. In all cases, the donor should be monitored during this time by either the collector or some other designated person. The donor's behavior while waiting (how much they drink, etc.) would be valuable information for the collector to record. During the monitoring period, the collector is permitted to conduct other collections.

At least once during the three hours, the collector must encourage the donor to make another attempt. The collector may extend the collection deadline briefly past the three hours with the carrier's concurrence only if it appears that the donor may be able to shortly provide an acceptable sample.

Once three hours have passed, the collector is to terminate the collection and report the situation to the carrier. The carrier is then responsible for having the donor evaluated by a physician acceptable to the employer. The role of the physician is to examine the donor and determine whether there is a legitimate medical or pre-existing psychological reason not to have provided an acceptable specimen volume.

The physician's final report must specifically answer the question at issue without equivocation. There must be a direct line between a medical condition or disease, a medication, or an anatomical problem and the inability to provide a sufficient sample. Dehydration is not an acceptable medical explanation. Situational anxiety is not an acceptable psychological explanation. The physician's report is to be submitted to the employer via the MRO, who may comment but not over-ride the physician's report. The employer is responsible for making the final

decision on whether the incident was a refusal.

4.7.2 ***Determine that the collector is capable of handling a refusal to test.***

Every effort should be made to encourage a recalcitrant donor to provide an acceptable specimen, including asking for assistance from the employer whenever possible. If the donor will not provide an acceptable urine specimen, it is to be considered a refusal, and must be reported to the employer.

If the donor will not sign the DTCCF but has provided what appears to be a bona fide specimen, the collector is to proceed normally and note the donor's unwillingness to sign in the Step 5 remarks. The same procedure should be followed if the donor will not initial the specimen label. In both circumstances, the specimen is acceptable and is to be sent to the carrier's laboratory for testing.

The donor cannot be made by the collector to sign a release of liability form. This would not constitute a Federal refusal, nor may the collector terminate the collection on that basis.

4.7.3 ***Determine that the collector is capable of handling an apparent attempt at substituting or adulterating the urine sample.***

Once the specimen is produced, the collector should visually inspect and smell the freshly voided urine. If it is apparent that the donor may have made an attempt to adulterate or substitute the specimen (the color is not consistent with normal urine, the urine foams too little or too much, there is a chemical smell, etc.), the collector must complete the collection if possible and initiate the procedures for a direct observation collection. Other observed behavior (i.e., a substitute urine in plain view, the presence of an adulterating substance in the donor's hand, etc.) may also lead to a directly observed second void.

The collector must obtain the concurrence of the collector's supervisor or a designated employer's representative before proceeding with a direct observation of a new void. If concurrence is obtained, the second collection should be conducted immediately, but certainly as soon as possible.

If the donor fails to cooperate or leaves, it is now considered a refusal and the employer is to be notified. If the donor cooperates, both specimens should be sent to the laboratory and the MRO notified by telephone or in the remarks section of both DTCCFs.

4.7.4 *Determine that the collection site or collection service is capable of handling a direct observation collection.*

Collection sites and mobile collection services must always be prepared to conduct an immediate direct observation collection when it is required by regulation. There should be no unnecessary delay in waiting for the collection site or collection service to produce a same sex observer.

Direct observation collections must be performed if directed by the employer (due to a previous positive, adulterated, substituted, or unsuitable for testing specimen); when an attempt to adulterate or substitute the specimen was discovered during the collection (and a supervisor or employer representative agrees); or when the specimen temperature is out of range (and the donor refuses to have their temperature taken or their body temperature is more than two degrees Fahrenheit from the urine temperature).

Direct observation collections must always be by a person of the same sex as the donor, and cannot be by either someone in the donor's direct chain of command or by a medical professional of the opposite sex. The direct observer must place themselves in a position where they can see the actual urine void into the collection cup.

If the collector inadvertently dismisses the donor before the direct observation collection can be initiated, the donor may be recalled for all test types (pre-employment, random, mandatory post-accident, return-to-work, and follow-up) to provide a direct observation specimen. Although there is no deadline for recall, the donor should be brought back as soon as possible.

If there have been multiple completed voids during the collection procedure (i.e., after an adulteration or substitution attempt), both the first obtained void and the directly observed void are to be submitted to the laboratory with appropriate remarks entered by the collector on the DTCCF.

Specimen Collection – Urine Summary Checklist

I. Preparation for Collections [4.5]

A. *Determine that the collection location is suitable for a properly secure and confidential urine collection for drugs.* [4.5.1]

B. *Determine that the collector has proper urine collection supplies, including Federal DTCCFs with tamper-evident seals, urine collection containers with temperature strips, split specimen transport bottles, and specimen shipment containers.* [4.5.2]

C. *Determine that the collector is properly qualified to conduct a Federal urine collection.* [4.5.3]

II. Federal Urine Collections [4.6]

A. *Determine that the collector properly conducts a urine collection, correctly incorporating Federal procedures and standards.* [4.6.1]

B. *Determine if the collector is able to distinguish between Federal and non-Federal collections.* [4.6.2]

III. Difficult Collection Problems [4.7]

A. *Determine that the collector is capable of handling a shy bladder collection.* [4.7.1]

B. *Determine that the collector is capable of handling a refusal to test.* [4.7.2]

C. *Determine that the collector is capable of handling an apparent attempt at substituting or adulterating the urine sample.* [4.7.3]

D. *Determine that the collection site or the collection service is capable of handling a direct observation collection.* [4.7.4]

5.0

SPECIMEN COLLECTION

BREATH

5.0 SPECIMEN COLLECTION – BREATH

5.1 OVERVIEW

Department of Transportation regulations found in 49 CFR 40.51 – 40.79 and FRA regulations found in 219.11 and 219.715 describe requirements for the collection of alcohol specimens under Part 219 for all but pre-employment testing (Subpart F) and mandatory post-accident testing (Subpart C). Subpart C testing employs a different type of specimen (blood) and alcohol testing is not authorized for FRA pre-employment at the present time.

FRA considers the carrier wholly responsible for the performance of its alcohol specimen collectors. This is true even if collection services, collection sites, or individual collectors have been contracted for by an outside third party administrator or consortium.

Required Federal alcohol tests may be conducted with approved saliva collection devices (screening only), approved non-evidential breath testing devices (screening only), or approved evidential-level breath testing devices (screening and confirmation). Evidential-level devices may only be employed by specially certified breath alcohol technicians (BATs).

The role of the BAT is to ensure that the breath samples obtained from the carrier's covered employees have been collected in a manner consistent with DOT and FRA regulations and guidelines. For each FRA alcohol collection, the collector must have been properly qualified; the collection location must have been properly prepared; the proper certified testing instrument must have been used; the specimen must have been obtained with the proper Federal standards maintained and procedures followed; and the collection documented on the proper Federal form.

BATs must be knowledgeable about all Federal alcohol collection requirements; be properly vigilant to detect attempts at damaging the integrity of the sample or the collection; and be capable of properly handling refusals, "shy lung" situations, or other unusual collection events in accordance with DOT and FRA regulations.

SPECIMEN COLLECTION – BREATH

5.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 40.3 – Definitions: Air Blank; Alcohol; Alcohol Concentration; Alcohol Use; Breath Alcohol Technician (BAT); Cancelled or Invalid Test; Confirmation (or Confirmatory) Test; Screening Test (or Initial Test)
- 40.51 – The Breath Alcohol Technician
- 40.53 – Devices to be Used for Breath Alcohol Tests
- 40.55 – Qualify Assurance Plans for BATs
- 40.57 – Locations for Breath Alcohol Testing
- 40.59 – The Breath Alcohol Testing Form
- 40.61 – Preparation for Breath Alcohol Testing
- 40.63 – Procedures for Screening Tests
- 40.65 – Procedures for Confirmatory Tests
- 40.67 – Refusals to Test and Uncompleted Tests
- 40.69 – Inability to Provide an Adequate Amount of Breath
- 40.97 – Invalid Tests
- 219.5 – Definitions: Alcohol; Alcohol Concentration (or Content); Alcohol Use; Confirmation Test; Refuse to Submit
- 219.11 – General Conditions for Chemical Tests
- 219.715 – Alcohol Testing Procedures

5.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier employs alcohol collectors for Part 219 testing that are experienced and fully knowledgeable of the regulations; can properly manage Federal alcohol collections, including calibration and maintenance of the instrumentation, in accordance with applicable standards of practice; can capably perform difficult or complicated collections (shy lung, refusals, etc.); and can collect samples in a professional manner, seeking a product which can achieve a scientifically sound and legally defensible test result.

5.4 RECORDS REQUIRED

The inspector should examine carrier alcohol test records (negatives and positives) to ensure the completeness and accuracy of the collection documentation. The inspector should interview one or more BATs performing this service for the carrier, and whenever possible, conduct a mock collection with one or more selected BATs in the carrier's system.

5.5 PREPARATION FOR COLLECTIONS

5.5.1 *Determine that the collection location is suitable for a properly secure and confidential alcohol collection.*

Alcohol testing can be conducted at any location, including carrier property, that affords visual and aural (hearing) privacy to the donor. The collection location must be secured from the public, other employees, or other unauthorized individuals who may innocently or purposefully interfere with the collection process. If it is an accident scene, the collector or the employer must attempt to provide visual and aural privacy to the greatest extent practicable. The collection area should also have access to an adjacent writing surface for filling out the Department of Transportation (DOT) Breath Alcohol Testing Form (BATF).

5.5.2 *Determine that the collector has the qualified equipment, proper collection supplies, and sufficient DOT BATFs to perform carrier alcohol tests.*

Under the Federal alcohol testing protocol, donors provide an initial screening sample and, if positive, a second confirmatory sample. Carriers may only employ qualified devices to test covered service personnel for the presence of alcohol. FRA permits the initial screening test to be conducted with either a qualified alcohol screening device (ASD) or a qualified evidential-level breath testing device (EBT).

A qualified ASD may be used in lieu of an EBT for screening only, but it may not be employed for confirmation tests. Qualified ASDs are included on a Conforming Products List published by the National Highway Traffic Safety Administration (NHTSA). Qualified ASDs utilize either breath or saliva as a test medium. Collectors eligible to use ASDs (Screening Test Technicians, or STTs) must have a different qualification than collectors using EBTs. Although permitted, very few carrier programs use ASDs for screening.

Most carriers use EBTs for both screening and confirmation. For that reason, the rest of this Section of the Manual will focus on EBTs and the personnel who are qualified to use them under FRA regulations.

SPECIMEN COLLECTION – BREATH

Qualified EBT devices are included on a Conforming Products List also published by NHTSA. EBTs are capable of the accurate quantitative detection of ethyl alcohol at 0.02% and above. The devices have the capability of printing test results in triplicate; assigning a unique and sequential number to each completed test (which is recorded in the device); printing out essential information on the test and the device in the result report; distinguishing alcohol from acetone and other volatiles at 0.02%; testing an air blank prior to each collection of breath; and performing an external calibration check. These and other features allow EBTs to produce test results that are scientifically sound and legally defensible.

Each qualified EBT has a comprehensive Quality Assurance Plan (QAP) developed by the manufacturer and approved by NHTSA, which establishes the scientific and operational standards under which the device must perform. The Plan specifies rigorous inspection, maintenance, operational, and calibration requirements for the instrument. The carrier is responsible for ensuring that for every EBT it utilizes, the QAP is being meticulously followed and that the external calibration checks are being precisely performed by qualified personnel.

The collector must maintain additional supplies to properly support the alcohol collection, and must be prepared to conduct multiple tests if necessary. Regardless of type of device(s) used (ASD and EBT, or EBT alone), collections must be fully documented on the DOT BATF. The specimen's unique identification number (UIN) is provided by the EBT itself.

5.5.3 ***Determine that the collector is properly qualified to conduct a Federal alcohol collection.***

The collector may be an employee of the carrier, a contractor, or be completely independent of the railroad. A supervisor in the donor's chain of command cannot be the collector.

Breath Alcohol Technicians (BATs) hold the only qualification to perform DOT alcohol confirmatory tests. These collections must be done on EBTs with breath as the medium to detect the presence of alcohol at 0.02% or above. To be qualified to perform Federal tests, the BAT must achieve a special certification by completing a course of instruction, demonstrating proficiency with the EBT they are being qualified to use, and passing a written practical examination. The BAT must

be knowledgeable in Federal requirements for a proper alcohol collection and experienced in conducting Federal collections (either alone or under supervision). The BAT should be able to provide an inspector with documentation of training and experience, and demonstrate their expertise by answering inspector questions or participating in a mock collection. The collector does not need to demonstrate or document their abilities to the donor or the donor's agent.

As a reference tool, the collector should have direct access to written procedures which describe Federal alcohol collection requirements. In addition, it would be recommended that the collector have direct and/or immediate access to a supervisor or someone else who would also be knowledgeable of Federal alcohol collection requirements.

5.6 FEDERAL BREATH ALCOHOL COLLECTIONS

5.6.1 *Determine that the collector properly conducts an alcohol collection, correctly incorporating Federal procedures and standards.*

The donor must first be properly identified through a picture ID, through direct supervisor identification, or other similar means. Verification of the donor's identity may not be by another worker, another donor, or through a non-photo identification. Supervisor identification may be by telephone as long as the identity of the donor is affirmed in sufficient detail.

The BAT may only collect a specimen from one donor at a time. Once a test sequence is started with an employee, it generally must be completed (including both screening and confirmatory tests, as necessary).

A properly completed copy of a Federal BATF can be found at Tab 2. The preliminary block on the BATF (Step 1) should be filled out before the donor provides a breath specimen. The donor must also fill out Step 2. If the donor will not sign Step 2 (which simply certifies that they are about to submit to breath alcohol testing), it is a refusal. If that occurs, the BAT terminates the collection, makes a note on the BATF, and informs the employer's representative immediately.

SPECIMEN COLLECTION – BREATH

If the testing has begun and the donor leaves, it is also a refusal. The BAT makes a note on the BATF and informs the employer immediately.

Once Step 1 and 2 are completed, the BAT and the donor affirm the sequential number displayed on the EBT. The BAT opens an individually sealed mouthpiece and attaches it to the instrument. The donor blows into the mouthpiece for at least six seconds. This is the screening test. Once the attempt is completed to the satisfaction of the BAT, the displayed result is read.

If negative (less than 0.02%), the testing is completed. The printed test from the EBT is affixed with tamper-evident tape to the designated location on the Form or is printed directly on the Form. The BAT then signs the certification statement in Step 3 and the donor completes the certification statement in Step 4. The negative result is reported by the BAT confidentially only to the carrier. The BATF is sent to the employer or the employer's service agent who retains it as a test record.

If there is a disparity in the test documentation produced by the EBT, the test may be declared invalid. For several FRA test types (reasonable suspicion, Federal reasonable cause, return to work, and follow-up), the collection must be repeated. For random testing, the covered employee need not reprovide.

If the screening test is 0.02% or greater, a confirmation breath sample must be collected. The same EBT can be used, or another qualified EBT device. The same BAT can perform the confirmation test, or another BAT can collect the specimen. If a new BAT performs the second test, the original BAT completes and signs the original BATF. The confirmation test is then conducted on a new BATF.

Under no circumstance may an employer take administrative action solely on the basis of a positive screening result.

The BAT must make the presumptively positive donor wait at least 15 minutes (but no longer than 30 minutes) before conducting the confirmation test on an EBT. Only unforeseen delays in completing the confirmation test, such as a unpredictable equipment failure, are acceptable reasons to extend beyond 30 minutes. Other reasons, such as the unavailability of an EBT or BAT, are likely unacceptable.

The donor is advised to not smoke, eat or drink, drive, perform covered service, or operate heavy equipment during the waiting period. If the donor refuses the BAT's

guidance, it is to be noted in the BATF's remarks section. During the wait, the donor should be monitored by the BAT, another collector, or carrier supervisory personnel.

Before performing the confirmation test, the BAT first ensures that the EBT registers 0.00% on an air blank. If the device registers greater than 0.00%, a second air blank is performed. If again greater than 0.00%, the EBT is to be replaced with a new EBT.

A fresh mouthpiece is to be used to collect the confirmation specimen. The donor is instructed to provide another breath sample, blowing forcefully for more than six seconds. The BAT and donor, having already read the new sequential number displayed on the EBT, read the confirmation result. The confirmation test result is the final result, and the only one to be reported to the carrier.

The EBT confirmation printout is affixed with tamper-evident tape to the BATF or printed directly on the Form. The BAT then signs and dates the collector certificate statement (Step 3), and the donor signs and dates the donor certification (Step 4). If the donor refuses to sign Step 4, it is not a refusal. The BAT simply annotates the donor's failure to sign and reports the EBT finding to the carrier's designated representative. If the confirmation result is less than 0.02%, it must be reported to the carrier as a negative result. If it is 0.02% or greater, the carrier's designated representative must be informed immediately by telephone or in person. No test result may be first reported to an employer's service agent (i.e. third party administrator).

If the result is 0.02% or greater, the donor must again be cautioned not to drive or perform covered service. The BAT must make every effort to contact the carrier immediately. Under no circumstances is the BAT expected to physically restrain the donor.

If the EBT ever fails an external calibration check, all positive results (0.02% and above) are declared invalid back to the last calibration check the device passed. It is therefore recommended that regardless of the calibration requirement in the QAP, that each EBT be checked as often as practical.

5.6.2 ***Determine if the collector is able to distinguish between Federal and non-Federal collections.***

The collector may not employ a Federal BATF for a non-Federal test, and vice-versa

5.7 DIFFICULT COLLECTION PROBLEMS

5.7.1 ***Determine that the collector is capable of handling a "shy lung" collection.***

If the donor makes a valid attempt to complete the breath test, but is unable to perform acceptably and provide an adequate amount of breath, the BAT must require a second attempt. If that too is unacceptable, the collection is concluded, the BAT records the problem in the remarks section of the BATF, and informs the carrier. The carrier then directs the employee to a physician for a medical examination similar to that required in the shy bladder situation (see Section 4.7.1)

5.7.2 ***Determine that the collector is capable of handling a refusal to test.***

Every effort should be made to encourage a recalcitrant donor to provide an acceptable specimen. Whenever possible, the carrier should be asked for assistance. If the donor refuses to sign Step 2 of the BATF, it is considered a refusal. If the donor signs Step 2, provides an adequate sample, but is unwilling to sign Step 4 of the BATF, it is not a refusal. Abandoning the collection process at any time is a refusal.

The donor may not be made by the collector to sign a release of liability form. This would not constitute a Federal refusal, and the collector may not terminate the collection on that basis.

Specimen Collection – Breath Summary Checklist

I. Preparation for Collections [5.5]

A. *Determine that the collection location is suitable for a properly secure and confidential alcohol collection.* [5.5.1]

B. *Determine that the collector has the qualified equipment, proper collection supplies, and sufficient DOT BATFs to perform carrier alcohol tests.* [5.5.2]

C. *Determine that the collector is properly qualified to conduct a Federal alcohol collection.* [5.5.3]

II. Federal Breath Collections [5.6]

A. *Determine that the collector properly conducts an alcohol collection, correctly incorporating Federal procedures and standards.* [5.6.1]

B. *Determine if the collector is able to distinguish between Federal and non-Federal collections.* [5.6.2]

III. Difficult Collection Problems [5.7]

A. *Determine that the collector is capable of handling a "shy lung" collection.* [5.7.1]

B. *Determine that the collector is capable of handling a refusal to test.* [5.7.2]

6.0

THE LABORATORY

6.0 THE LABORATORY

6.1 OVERVIEW

Department of Transportation regulations found in 49 CFR 40.21, 40.27, 40.29, 40.31, 40.39 and FRA regulations found in 49 CFR 219.701, 219.705, and 219.711 describe requirements for laboratories conducting urine drug testing for all but FRA mandatory post-accident testing.[1] FRA considers the carrier wholly responsible for the performance of the laboratory in all but FRA's mandatory post-accident program. This is true even if the laboratory has been contracted for by an outside third-party administrator or consortium. The carrier may employ one or more laboratories.

Laboratories conducting testing under the pre-employment, reasonable suspicion, Federal reasonable cause, and random portions of the FRA rule must hold a special qualification (DHHS/SAMHSA certification). The laboratory is responsible for providing collection supplies (Drug Testing Custody and Control Forms and collection kits) to the carrier's collection sites, transporting specimens from the collection sites to its facility, analyzing the specimens in accordance with DHHS and DOT requirements, and reporting scientifically sound and legally defensible test results to the carrier's Medical Review Officer (MRO). The laboratory is also responsible for retaining positive specimens for at least one year and all testing records for any DOT regulated sample for at least two years.

6.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 219.701 – Standards for Urine Drug Testing
- 219.705 – Drugs Tested
- 219.711 – Confidentiality of Test Results
- 40.3 – Definitions: Aliquot; Blind Sample or Blind Performance Test Specimen; Chain of Custody; Confirmation (or Confirmatory) Test; DHHS; Screening Test (or Initial Test); Shipping Container; Specimen Bottle

[1] FRA mandatory post-accident testing laboratory regulations are primarily found in 49 CFR 219.211 and in Appendix B to Part 219. The FRA post-accident program is discussed in Section 10.0 of this manual.

- 40.21 – The Drugs
- 40.27 – Laboratory Personnel
- 40.29 – Laboratory Analysis Procedures
- 40.31 – Quality Assurance and Quality Control
- 40.39 – Use of DHHS – Certified Laboratories

6.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier employs a laboratory for Part 219 testing that is fully qualified under the regulations, has agreed to allow inspection by FRA and/or the carrier as required by the rule, produces test results that are scientifically sound and legally defensible, and otherwise performs its duties in full accord with applicable DHHS, DOT, and FRA regulations and the highest scientific standards of practice.

6.4 RECORDS REQUIRED

The inspector should examine test records provided by the laboratory to the Medical Review Officer (MRO) to ensure their completeness and accuracy. The inspector should also examine the laboratory-carrier contract, if applicable, and review the quarterly statistical summary reports provided the carrier by the laboratory.

6.5 THE LABORATORY

6.5.1 *Determine if the laboratory utilized by the carrier holds DHHS/SAMHSA certification.*

The Rule requires that any laboratory testing specimens under Part 219, including FRA's special post-accident laboratory, must hold certification by the Department of Health and Human Services/Substance Abuse and Mental Health Services Administration (DHHS/SAMHSA). The certification, part of the National Laboratory Certification Program (NLCP), must be in place during the time that any testing is performed by the laboratory for the carrier.

Although not required by the Rule, it is recommended that the carrier require the laboratory to inform it if their certification is ever suspended or revoked.

6.5.2 Determine that the laboratory is properly cancelling tests for unresolved documentation errors on the Drug Testing Custody and Control Form (DTCCF) or problems with the specimen.

The laboratory, in its receiving/accessioning process, is responsible for cancelling testing for specimens where either the DTCCF or the sample itself has unresolvable problems. When the problems are resolvable, the laboratory is responsible for making a reasonable effort to obtain signed statements remedying the problem.

The following problem areas can be remedied with a signed statement:

- Collector's signature is absent.
- Step 6 of the DTCCF is incomplete (needs two signatures, shipping entry, date).
- Donor SSN or ID is missing from Step 1 of the DTCCF.

The following problem areas cannot be remedied and will cause automatic cancellation:

- The specimen ID number on the bottle and on the DTCCF do not match.
- There is no specimen ID number on the specimen bottle.
- There is not enough specimen to test.
- The specimen bottle seal is broken or shows evidence of tampering.

6.5.3 *Determine that the laboratory has agreed in writing to unannounced inspections by the carrier and FRA.*

In accordance with 219.701(b), the carrier must have in writing, either in its contract or in separate correspondence, that the laboratory agrees to unannounced inspections by the carrier and FRA.

6.5.4 *Determine that the laboratory is submitting quarterly summary statistical reports to the carrier, and the carrier is reviewing and retaining these reports.*

In accordance with 40.29 (g)(6), the laboratory is responsible for submitting an employer-specific aggregate statistical summary each quarter directly to the employer or, if applicable, to the employer via the carrier's third party

administrator. This report must be in a format prescribed by the Part 40 regulation and is to be maintained in hard copy by the carrier for at least two years. Older laboratory report formats, notably that which differentiates screening positives from confirmatory positives for each drug class, are no longer permitted.

6.5.5 ***Determine that the laboratory has not issued a false positive report on any carrier urine specimen in the audit timeframe.***

Based on the MRO's assessment, the carrier should be made aware of any true false positive reports made by the laboratory to the MRO in the audit timeframe. A true false positive is a result reported by the laboratory that in actuality never did contain the analyte(s) of interest. The error, whether clerical or scientific, is considered catastrophic and must be reported by the carrier to the FRA for further investigation by the Department of Transportation and the Department of Health and Human Services. A split specimen that failed to reconfirm when sent to a referee laboratory is not 'per se' evidence of a false positive as long as the drug was indisputably present at one time in the donor's urine.

6.5.6 ***Determine that the carrier has been submitting blind quality control samples to the laboratory at a rate and in a manner consistent with the regulation.***

Part 40 regulations (40.31 (d)) require each employer to submit blind specimens to their contract laboratory at a 3% rate. That is, for every one hundred Federal tests (pre-employment, random, reasonable suspicion, etc.), three must have been blinds. The samples may be submitted singly or in groups (i.e, of three or more) and need not be distributed evenly throughout each hundred carrier tests.

Blind samples may be obtained from a third party supplier or may be provided specially for this purpose by carrier personnel. Completed chain-of-custody forms for blind specimens must generally reflect carrier operations, and it should not be obvious to the laboratory that the submitted sample is a blind. If a third-party administrator or other party is responsible for submitting blinds on behalf of the carrier, documentation of the submissions (likely including copies of chain-of-custody forms) and the laboratory's findings should be regularly received and maintained by the carrier. In some circumstances, it may be permissible for a third-party administrator to submit blinds to the laboratory for a group of carriers through a separate fictitious railroad employer, as long as the audited carrier's blind submission obligations can be clearly differentiated from other consortium members.

The Laboratory Summary Checklist

I. The Laboratory [6.5]

A. *Determine if the laboratory utilized by the carrier holds DHHS/SAMHSA certification.* [6.5.1]

B. Determine that the laboratory is properly cancelling tests for unresolved documentation errors in the Drug Testing Custody and Control Form or problems with the specimen. [6.5.2]

C. *Determine that the laboratory has agreed in writing to unannounced inspections by the carrier and FRA.* [6.5.3]

D. *Determine that the laboratory is submitting quarterly summary statistical reports to the carrier, and the carrier is reviewing and retaining these reports.* [6.5.4]

E. *Determine that the laboratory has not issued a false positive report on any carrier urine specimen in the audit timeframe.* [6.5.5]

F. *Determine that the carrier has been submitting blind quality control samples to the laboratory at a rate and in a manner consistent with the regulation.* [6.5.6]

7.0

MEDICAL REVIEW OFFICER

(MRO)

7.0 THE MEDICAL REVIEW OFFICER (MRO)

7.1 OVERVIEW

Department of Transportation regulations found in 49 CFR 40.29 and 40.33 and FRA regulations found in 49 CFR 219.707, 219.708, 219.709, and 219.711 describe requirements for Medical Review Officers under the urine testing portions of the FRA rule. FRA considers the carrier wholly responsible for the performance of its Medical Review Officer (MRO), including for mandatory post-accident testing. This is true even if the MRO has been contracted for by an outside third party administrator or consortium.

The role of the MRO is to receive all urine drug test results from the carrier's laboratory. In the case of negative results, the MRO's role is purely administrative, reporting the finding to the employer. With laboratory positive test results, however, the MRO is responsible for determining if the donor has a verifiable, legitimate medical explanation for the positive test. If not, the result must be reported to the carrier as a verified positive. If the donor has an acceptable medical explanation which can be verified, the MRO must report the finding as a negative test in a manner which is identical to a report made to the carrier on a laboratory negative result. All test findings, negative or positive, must be reported to the carrier in a confidential manner.

The MRO is also responsible for coordinating all requests for split specimen testing. The MRO has no role in Federal alcohol tests, and a limited role in FRA mandatory post-accident testing and shy bladder situations.

7.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 40.3 – Definitions: Cancelled or Invalid Test; Chain of Custody; Confirmation (or Confirmatory) Test; Medical Review Officer
- 40.29 – Laboratory Analysis Procedures
- 40.33 – Reporting and Review of Results
- 219.5 – Definitions: Consortium; Drug; Medical Review Officer or MRO; Refuse to Submit

- 219.707 – Review by MRO of Urine Drug Testing Results
- 219.708 – Employee Requests for Testing
- 219.709 – Retest
- 219.711 – Confidentiality of Test Results

7.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier employs a MRO for Part 219 testing that is fully qualified under the regulations; properly manages test results and chain-of-custody documents; interprets drug test results and, when applicable, interviews positive donors in accordance with applicable regulations, published guidance, and Federal standards of practice; reports findings in an expeditious and confidential manner, and performs all other MRO responsibilities capably.

7.4 RECORDS REQUIRED

The inspector should examine test records (negative, positive, and MRO downgrades) to ensure their completeness and compliance with Federal regulations and standards of practice. The inspector should interview the MRO (or one or more physicians performing that role for the carrier) and members of the MRO staff. An inspection of the MRO's physical facility may be necessary. Copies of MRO reports made to the carrier should be reviewed.

7.5 MRO QUALIFICATIONS AND ORGANIZATION

7.5.1 *Determine if the MRO(s) utilized by the carrier hold the proper qualifications.*

Department of Transportation regulations require a MRO to be a physician (MD or DO) holding a valid medical license at least in the state they are residing, knowledgeable of substance abuse disorders, and capable of properly interpreting laboratory positive findings in conjunction with the donor's medical history and other relevant biomedical information.

The MRO does not need to be trained or hold a special MRO certification from a medical specialty or private organization, although such training is often useful in the performance of MRO responsibilities.

7.5.2 ***Determine if the MRO's staff organization is consistent with the requirements of the regulations and DOT published guidance for MROs.***

A carrier can utilize one or more qualified physicians to act as MRO. Each MRO can be an employee of the carrier, a subcontractor to the carrier's Medical Director, or completely independent from the carrier. Regardless of the relationship, the MRO staff must be under the direct daily supervision of a physician qualified to be a MRO. Without a qualified MRO resident full-time, a third party administrator, consortium, or even the Medical Department of the carrier is not permitted to perform MRO duties. This includes but is not limited to receiving test results directly from the laboratory, receiving or reviewing chain-of-custody documents from collection sites, contacting or interviewing positive donors, or reporting test results to the carrier.

Test results must be received from the laboratory in a secure manner but electronic transmission is permitted (i.e., fax, laboratory printer, computer-to-computer download, etc.). An unsecure internet transmission is not permitted.

Test results and MRO records should not be accessible to the public or staff personnel who are not directly responsible for MRO duties. This includes, but is not limited to, computer databases, file cabinets, fax machines, etc.

7.6 MRO DETERMINATIONS

7.6.1 ***Determine that the MRO is administratively reviewing and properly reporting negative laboratory test results.***

The MRO or a staff member under the MRO's direct supervision should review each donor's MRO copy of the Drug Testing Custody and Control Form, or DTCCF (Copy 4 or equivalent) and its matching laboratory report prior to releasing the negative result to the employer. The MRO's office needs to have only these two documents to report the result, but the MRO must also retain Copy 2 of the DTCCF (signed by the laboratory's certifying scientist) when it arrives from the laboratory. In unusual cases where the MRO copy of the DTCCF (Copy 4) is not available, a facsimile or original of another copy of the DTCCF is acceptable (Copies 5, 6, or 7).

The MRO should not ordinarily cancel negative tests if there are problems with an individual Copy 4 (or equivalent) or Copy 2 of the DTCCF, or the laboratory report, but systemic problems should be remedied with the collection site or the laboratory. Cancellation of a negative test could occur only if the true identity of the donor cannot be ascertained.

7.6.2 ***Determine that the MRO is properly verifying and reporting positive test results.***

The principal role of the MRO in Federal urine testing is to determine if there is a legitimate and verifiable medical explanation for a donor's positive test. In the case of a positive laboratory result, the MRO may not conduct an interview with the donor until the original or a facsimile of the Copy 4 of the DTCCF (or equivalent) and the laboratory report are available. The MRO may not report the final positive determination until the Copy 2 has arrived from the laboratory.

Once all of the required paperwork is available, the MRO is expected to complete the case without delay. It is expected that most cases will be resolved within one or two work days.

Most serious documentation problems with the DTCCF may be recoverable by a signed statement from the collector, laboratory certifying scientist, or donor. If not resolved, however, the test may have to be cancelled by either the laboratory or the MRO. The absence of the donor's signature on Step 4 (unless the Form is annotated that the donor refused to sign) or the absence of the certifying scientist's signature on Step 7 are potentially fatal flaws for the MRO on positive tests.

The donor may be contacted by either the MRO or a staff member under the MRO's direction. The MRO must be the one interviewing the donor (not a staff member), and FRA expects the MRO to make every reasonable attempt to complete the interview. The three rare circumstances for not interviewing a positive donor are a refusal to talk to the MRO, the donor does not call the MRO within five days after being directly notified by an employer's representative, or the donor cannot be contacted by either the MRO or the carrier and 14 days have passed.

The MRO may receive urine drug concentrations routinely from the laboratory for only the opiates. All other requests for concentrations must be made directly for each specimen. The MRO must not request quantitations for specimens testing below the cutoff.

MEDICAL REVIEW OFFICER

There is no doctor-patient relationship in a MRO interview. Interviews may be face-to-face or by telephone. The MRO should document all attempts to contact the donor and retain acceptable notes from the interview. The MRO should record the donor's reasons for why the test was positive, any medical information offered, and clearly rule out all acceptable medical explanations.

In making their verification determination, the MRO may only talk to the specimen donor. The MRO may not conduct the interview with their union representative, attorney, or any other person present. The sole exception would be a translator acceptable to the MRO. A donor's unwillingness to cooperate with this requirement constitutes a refusal to be interviewed.

There are acceptable medical explanations for four of the drugs tested by FRA (marijuana, cocaine, amphetamines, and opiates). One drug (PCP) does not have a medical explanation. Opiates must have clinical evidence of abuse, in addition to the positive result, before it may be verified as a positive by the MRO. Medical explanations offered by a donor must be affirmed with the medical or dental practitioner, pharmacist, etc.

Passive exposure to a smokable drug (marijuana, cocaine, heroin, amphetamine) will not cause a positive test under any realistic circumstances and is not an acceptable medical explanation. Claims of accidental or innocent ingestion may not normally be considered by the MRO, and should never result in a MRO downgrade without immediately available, incontrovertible evidence. Claims of the use of hemp products or claims of medical use of marijuana under state law are not acceptable medical explanations under Federal testing programs and must be reported as positive. Use of someone else's medication, regardless of the circumstance, is clinical evidence of abuse under FRA regulations and must be reported to the carrier as a positive.

MRO downgrades (laboratory positives where the MRO has verified a legitimate medical explanation) must be reported to the carrier identically as if the donor's specimen had tested negative originally. Under no circumstances may a MRO downgrade a laboratory positive based solely on the donor's assurances of taking a particular medication or undergoing a particular medical or dental procedure. Every downgrade must be carefully verified.

7.6.3 ***Determine that the MRO is reporting test results to the carrier in a confidential manner.***

The MRO may report test results, both negative and positive, to the carrier verbally. Although not required by the regulation, a hard copy of the MRO's final determination sent to the carrier is strongly recommended.

The MRO must report test results in a confidential manner to a designated railroad official or limited backup(s). The MRO may not report test results to the carrier through a third party administrator or other service agent performing a management role. The carrier is permitted to authorize simultaneous reporting to such entities, but under no circumstances may they receive the reports before the employer.

The MRO function does not have the authority to relieve an employee from covered service directly after a verified positive test. Test results may only be disseminated to carrier personnel on a strict need-to-know basis.

Employers may not receive the concentration of a drug or metabolites for a particular positive specimen until after the donor has taken an employment action to challenge the test determination.

FRA regulations require that the MRO send copies of test determinations (negative or positive) to each covered employee tested under Part 219. The MRO may permit the carrier to perform this task for them.

7.6.4 ***Determine that the MRO notifies positive donors of their right to a test of the split specimen, accepts requests for a minimum of 72 hours, and processes their requests with the laboratory.***

In the case of a MRO-verified positive determination, the donor has the right to have the split specimen tested at another DHHS/SAMHSA certified laboratory. The donor has 72 hours to decide to test the split, but the MRO can expand the decision window if there are extenuating circumstances. Who pays for the test cannot be a barrier to the donor's right to have a split tested; if the donor cannot pay but still wants the test, the carrier must ensure that split testing is performed.

Adulterated or substituted specimens are not eligible for their splits to be tested. No other drugs or substances, or human identity factors (i.e., DNA) are permitted to be tested in either the split or the original specimen.

The sole purpose of the split test is to reaffirm the presence of the drug(s) or drug metabolite(s) found to be present by the original laboratory. Therefore, if the analyte(s) are reconfirmed by the referee laboratory, the donor remains in violation of FRA prohibitions regardless of concentration found in the split test.

7.6.5 ***Determine that the MRO properly handles and reports dilute, cancelled, and adulterated or substituted specimens.***

If a specimen is dilute, the MRO is to inform the carrier of the test result (either negative or positive) and that the next time the applicant or employee is selected for a Federal drug test, the employer may require the specimen to be collected under direct observation.

If a specimen cannot be tested due to a fatal or unrecoverable flaw, the MRO reports the reason to the carrier. Certain tests (pre-employment, return-to-duty, and follow-up, but not random) must be recollected.

If a specimen is reported by the laboratory as unsuitable for testing, the MRO must interview the donor. If there is no medical reason for the problem, the MRO must report the specimen's unsuitability and the employer must immediately have the donor retested under direct observation.

If the specimen is reported to the MRO as substituted (it was not a human product) or adulterated (the pH was not consistent with human urine or a substance was found which must have been introduced purposefully as a contaminant), it must be reported to the carrier as such, and the test must be treated by the carrier as a refusal.

7.6.6 ***Determine that the MRO is retaining negative test records for at least one year and positive test records for at least five years.***

All records associated with negative and positive tests (DTCCFs, laboratory reports, MRO interview notes and memoranda, etc.) must be retained in original hard copy for the designated timeframes. Scanned documents are not acceptable.

7.7 OTHER MRO RESPONSIBILITIES

The MRO role in a mandatory post-accident (Subpart C) test is somewhat different than the role for other Part 219 testing. In general, the MRO has no responsibility for remediating problems with chain-of-custody documents (FRA Forms 73 and 74). With regard to surviving employees, the MRO's role is generally the same as for other Part 219 testing. The MRO is encouraged to contact the FRA's contract post-accident laboratory for assistance in the interpretation of both positive blood and urine findings with FRA's broader post-accident testing panel and different cutoffs. The carrier's MRO is expected to have no role in the interpretation of positive results from fatalities, where blood, urine, and tissue samples may have been collected.

The MRO has a limited role for shy bladder situations, but must coordinate the sending of medical reports from the donor's physical or psychological examination to the carrier.

The Medical Review Officer Summary Checklist

I. MRO Qualifications and Organization [7.5]

A. *Determine if the MRO(s) utilized by the carrier hold the proper qualifications.* [7.5.1]

B. *Determine if the MRO's staff organization is consistent with the requirements of the regulations and DOT published guidance.* [7.5.2]

II. MRO Determinations [7.6]

A. *Determine that the MRO is administratively reviewing and properly reporting negative laboratory test results.* [7.6.1]

B. *Determine that the MRO is properly verifying and reporting positive test results.* [7.6.2]

C. *Determine that the MRO is reporting test results to the carrier in a confidential manner.* [7.6.3]

D. *Determine that the MRO notifies positive donors of their right to a test of the split specimen, accepts requests for a minimum of 72 hours, and processes their requests with the laboratory.* [7.6.4]

E. *Determine that the MRO properly handles and reports dilute, cancelled, and adulterated or substituted specimens.* [7.6.5]

F. *Determine that the MRO is retaining negative test records for at least one year and positive test records for at least five years.* [7.6.6].

8.0

PRE-EMPLOYMENT

TESTING

8.0 PRE-EMPLOYMENT TESTING

8.1 OVERVIEW

FRA regulations found in 49 CFR 219.501 – 219.503 (Subpart F) describe requirements for FRA pre-employment testing. FRA's intent is to ensure that no applicant (employee, contractor, or volunteer) can be placed into covered service by hire, by first-time transfer, or by assignment without first successfully passing a FRA-required pre-employment drug test. FRA's goal for an effective carrier program is that each applicant for covered service has tested negative on a Federal drug test before any covered service is performed and that no applicant for a non-covered service position is asked to take a Federal drug test. Under current regulations, no pre-employment alcohol testing may be conducted under Federal authority.

8.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Positive Rate; Refuse to Submit
- 219.501 – Pre-Employment Tests
- 219.502 – [Reserved]
- 219.503 – Notification; Records
- 219.504 – [Reserved]
- 219.505 – Refusals
- 219.701 – 219.715 – Subpart H – Procedures and Safeguards for Urine Drug Testing and for Alcohol Testing

8.3 INSPECTION GOAL

The goal for inspecting this element is to determine that all personnel performing covered service for the carrier, with the single exception noted below, must have a properly conducted negative Federal drug test on file from the MRO before performing any covered service. This includes new hires, transferring employees, contractors, and volunteers. The single allowed exception is an unpredicted strike where it is essential that the carrier maintain continued operations. In addition, non-covered personnel must not be made to take what appears to be a Federal drug test for a company policy testing program.

8.4 RECORDS REQUIRED. The inspector should obtain a complete list of all system personnel hired or transferred into covered service by the carrier during the audit timeframe. The inspector should also obtain a complete list of all personnel hired into non-covered service positions during that same audit time-frame. The inspector should inquire about any emergency hiring that occurred, and obtain a complete list of any personnel assigned by the carrier to perform covered service temporarily. Interviews with headquarters and field staff may be necessary. Copies of test results and/or certifications from the MRO are likely to be required.

8.5 PRE-EMPLOYMENT TESTING

8.5.1 ***Determine whether the carrier's identification of covered service positions for pre-employment testing is reasonable, complete, and consistent with FRA regulations.***

All covered service positions throughout the carrier's system should be clearly identified by the carrier as requiring FRA pre-employment testing. The list should include all geographically diverse job categories and individual covered service job assignments in the carrier's system. For purposes of the rule, all covered service requires a pre-employment test, including those positions filled by contractors and volunteers.

8.5.2 ***Determine whether all personnel hired, transferred for the first time, or assigned into covered positions in the audit timeframe had taken a FRA pre-employment test. Assess whether the test result from the MRO was on file with the carrier on or before the same day the individual began covered service.***

The carrier should have a mechanism in place to ensure that Federal pre-employment testing is conducted for all covered positions in the carrier's system. All tests must be on a Federal Drug Testing Custody and Control Form (DTCCF). Attention should be paid to pre-employment tests in all carrier geographic areas, job categories, and covered job assignments. The carrier should be especially vigilant with all positions being filled by contractors or volunteers, or are being out-sourced.

Under FRA regulations, a Federal pre-employment test is a one-time requirement for each employer. A covered service employee need never take a second pre-employment test for a carrier even if returning to covered service after a lay-off,

termination, etc. Personnel performing covered service for a carrier before March 1, 1986, are not required to have a Federal pre-employment test.

The carrier must have a negative Federal test pre-employment result on file from the MRO before allowing an applicant, employee, contractor, or volunteer to perform covered service.

8.5.3 *Determine whether any verified positive applicants or refusals performed covered service without meeting the FRA's re-eligibility requirement.*

Carriers may not immediately test again and place into covered service those applicants who have a verified positive result on a Federal pre-employment test, have refused the collection, or have attempted to either adulterate or substitute their urine specimen (another form of refusal). In order to perform covered service after a verified positive or a refusal, the applicant must have met the requirements of the Substance Abuse Professional (SAP) of record, have been recommended for eligibility by the SAP, and have passed a Federal return-to-work test.

The carrier is under no obligation to consider an individual's application for covered service further after the original positive or refusal determination. Carriers are also under no obligation to complete a shy bladder medical assessment for applicants.

8.5.4 *Determine whether any non-covered service pre-employment tests are being improperly conducted using Federal custody and control collection forms.*

The carrier should have a mechanism in place to ensure that non-covered service hires are not tested on a Federal form. Use of the Federal DTCCF for a non-regulated carrier pre-employment test transforms it to FRA authority, regardless of the original reason for the collection.

8.5.5 ***Determine whether replacement workers (i.e., for a predicted strike) were allowed to perform covered service without a valid negative pre-employment drug test on file.***

When a predicted shortfall of covered service personnel occurs (i.e., during an expected strike), carriers must exercise due diligence to ensure that before performing covered service, all replacement workers have a Federal pre-employment test on file for that carrier or are qualified via a previous acceptable Federal drug test taken within the preceding 30 days for another employer.

If the shortfall is unpredicted, the carrier may place personnel in covered positions temporarily without a pre-employment test on file if they can document that the delay to accomplish the test would have severely impacted carrier operations. In such a circumstance, the FRA may permit the carrier no more than a 30 day waiver to conduct pre-employment tests on all replacement personnel.

8.5.6 ***Assess whether the carrier can provide an adequate auditable record on the implementation of its FRA pre-employment testing program.***

Records which demonstrate compliance with the audit elements described in this section are essential, and the carrier must be capable of documenting audit elements and providing complete systems which manage supporting records. Inadequate record systems should be considered as noncompliance by the carrier.

Pre-Employment Test Summary Checklist

I. Pre-Employment Testing [8.5]

A. *Determine whether the carrier's identification of covered service positions for pre-employment testing is reasonable, complete, and consistent with FRA regulations.* [8.5.1]

B. *Determine whether all personnel hired or transferred into the identified covered positions in the audit timeframe had taken a FRA pre-employment test. Assess whether the test result from the MRO was on file with the carrier on or before the same day the individual began covered service.* [8.5.2]

C. *Determine whether any verified positive applicants or refusals performed covered service without meeting the FRA's re-eligibility requirement.* [8.5.3]

D. *Determine whether any non-covered service pre-employment tests are being improperly conducted using Federal custody and control collection forms.* [8.5.4]

E. *Determine whether replacement workers (i.e., for a predicted strike) were allowed to perform covered service without a valid negative pre-employment drug test on file.* [8.5.5]

F. *Assess whether the carrier can provide an adequate auditable record of the implementation of their FRA pre-employment testing program.* [8.5.6]

9.0

RANDOM TESTING

9.0 RANDOM TESTING

9.1 OVERVIEW

FRA regulations found in 49 CFR 219.601 – 219.611 (Subpart G) describe requirements for FRA random drug and alcohol testing. FRA believes that random testing is the best deterrence weapon available to combat the use of drugs and abuse of alcohol by all railroad employees performing covered service. FRA's goal for an effective carrier program is that every covered employee believes that they may be called for a random drug and/or alcohol test without advance warning at any time they are on duty.

9.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Positive Rate; Refuse to Submit; Violation Rate
- 219.601 – Railroad Random Drug Testing Program
- 219.602 – Administrator's Determination of Random Drug Testing Rate
- 219.603 – Participation in Drug Testing
- 219.605 – Positive Drug Test Results; Procedures
- 219.607 – Railroad Random Alcohol Testing Programs
- 219.608 – Administrator's Determination of Random Alcohol Testing Rate
- 219.609 – Participation in Alcohol Testing
- 219.611 – Test Result Indicating Prohibited Alcohol Concentration; Procedures
- 219.701 – 219-715 – Subpart H – Procedures and Safeguards for Urine Drug Testing and Alcohol Testing

9.3 INSPECTION OR AUDIT FOCUS

There are four major elements in a carrier's random testing program which must be assessed:

- The Random Testing Plan
- Random Testing Pools
- Random Selections
- Program Implementation and Collections

9.4 THE RANDOM TESTING PLAN

9.4.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier has a FRA-approved Random Plan for Drug and Alcohol Testing as required by 219.601, whether the Plan has been updated to reflect the current program design, whether the Plan matches current carrier practices, and whether the Plan achieves the level of deterrence expected by FRA.

9.4.2 Records Required. The inspector should obtain a copy of the latest Random Plan maintained by the carrier and a copy of the latest approved Plan on file with FRA headquarters (obtained from the FRA Drug and Alcohol Program Manager (DAPM)). The alcohol program is likely available as an amendment to the master drug Plan. The Plan on file with the DAPM is considered to be the operational document for purposes of assessment and to measure against current carrier practices.

9.4.3 The Random Plan

9.4.3.1 ***Determine that the carrier has a FRA-approved drug and an approved alcohol Random Plan.***

9.4.3.2 ***Determine that Plan amendments are being submitted properly for FRA approval.***

Every employer of covered service personnel must have a FRA-approved drug and a FRA-approved alcohol Random Plan on file with the DAPM. Program amendments of significance (e.g., changes in service providers, new organization of the pool(s), new selection procedures, etc.) must be approved by FRA at least 30 days before their implementation.

9.4.3.3 ***Determine that the Plan is complete and up-to-date on its face.***

Each plan should contain descriptive information and sufficient detail for the inspector to determine that:

a. The carrier has identified which positions or types of positions are to be incorporated into the random testing program and that all employees performing covered service throughout the carrier's system are being included. Contractors, volunteers, or other individuals performing covered service not directly employed by the carrier are also required to be randomly tested in a FRA-

approved program.

b. The carrier has identified which positions or types of positions are identified as providing only "de minimus" covered service, and how the carrier intends to handle these personnel within their random program.

c. The random pools used for selection have been properly constructed (see 9.5) and the Plan describes a specific mechanism so that they are regularly updated by the carrier.

d. The selection method appears to offer an objective means to select employees without apparent bias.

e. The selection method clearly states how employees are to be selected for drug testing, for alcohol testing, or for both.

f. The implementation plan describes how and when the selectee is to be notified to test, how the collections are to be accomplished, and identifies the circumstances for not testing the individual or pool entry.

g. The implementation plan offers an objective means to collect specimens from each selectee without discretion by the field supervisors or other management personnel on who is to be tested.

h. The carrier is providing a reasonable deterrent to its covered service employees by testing throughout its entire operation on all shifts, on all days it operates.

i. The carrier has identified specific service providers for the laboratory analysis, MRO duties, and SAP responsibilities. Identification of individual collection sites is not necessary, nor is it a priority to update the list if it is included in the Plan.

j. The carrier has a procedure for the proper retention of records.

Because a Plan has been previously approved by FRA does not mean that it is acceptable under current FRA random program standards. Inadequate, incomplete, or missing program elements must be remedied. The Plan on file with FRA must reflect current carrier practices, including the detailed characterization of each element described above.

9.5 THE RANDOM TESTING POOLS

9.5.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier has constructed its random testing pool(s) properly, whether all covered service personnel are included, and whether any personnel who are performing "de minimus" covered service are unnecessarily diluting the pool(s).

9.5.2 Records Required. The inspector should obtain a copy of each random pool the carrier utilized during the audit period. Based on how the pools are organized, the inspector may need additional documents from the carrier such as operations schedules, yard employee lists, payroll rosters, etc.

9.5.3 Pools

9.5.3.1 *Determine that each FRA random pool employed by the carrier completely and accurately includes or encompasses all covered service personnel who should be in that pool.*

The carrier must have a mechanism in place to ensure that each of its pools is complete and does not include inappropriate or non-covered service personnel. The carrier's specification of covered positions/employees must be uniform across its system. The carrier's interpretation of who is to be included in each of its pools must be clear and unambiguous.

The carrier must ensure that its pools are all-inclusive, and have encompassed all carrier geographical locations, work centers (urban and rural), and more unusual operations (seasonal hiring locations, locations where contractors or volunteers perform covered service functions, remote services, newly acquired operations, shop operations, etc.).

A proportion of each pool for each selection period audited should be checked for compliance. The following guidelines are offered:

a. Whoever is performing safety-sensitive "covered service," regardless of title or status, is subject to FRA random testing. This includes contractors and volunteers.

b. Covered service and non-covered service personnel cannot be mixed in the same pool.

c. Multiple pools are permitted, with no limit on number as long as each pool meets the other criteria for random pools outlined in the text.

d. Employees need not be placed in separate pools for drug and alcohol testing selection.

e. Employees from different DOT operating administrations can be placed in the same pools (i.e., FRA and FHWA). If the carrier does this, however, it is preferred that they not mix personnel who are to be tested at different drug and alcohol rates (i.e., have some pool entries that are to be tested at a 25% rate and some at a 10% rate). If they do mix these personnel, the carrier must test the entire pool at the highest selection rate for any of the groups with employees in the pool.

f. Besides individual employees, specific jobs (i.e., third shift train dispatcher at XYZ location) or operational units (i.e., trains) may also be entries in a population pool. Different types of entries may be mixed together as long as all pool entries are of approximately the same size.

   Larger entries must be broken into sub-entries if necessary to achieve a balance to the rest of the pool (i.e., the entire third shift of 14 dispatchers as a single entry could be broken up into four to six entries to match with a pool filled with two to three person train crews). This must be done in a way, however, which ensures that the makeup of each of the smaller entries remains absolutely stable, so that parts of a pool entry do not "float" between several smaller entries.

g. Pool entries may not be constructed in a way which could result in a field manager or supervisor eventually having discretion in who would be actually collected. That is, a pool entry must be tested in its entirety and arbitrarily selecting only a portion of the entry to test is not permitted even if it is part of the carrier's approved plan.

9.5.3.2 ***Determine that carrier pools do not mix personnel regularly performing covered service with personnel who provide "de minimus" service.***

As a general rule, no random testing or other Part 219 coverage is required of any employee if they perform covered service less than once a quarter. FRA considers this "de minimus" service. Carriers are permitted to randomly test such personnel, but they must not be placed in a pool with other entries that are performing covered duties more regularly. An exception can be made if the rare periods of covered service performed by an ordinarily "de minimus" employee are excessive or in some other way the carrier determines that the individual's covered service performance may substantially affect safety.

In addition, true "de minimus" individuals may still be permitted to perform covered service even if they are not subject to random testing, as long as they continue to meet the "de minimus" rule.

Carriers are strongly discouraged from placing large numbers of yard or shop personnel in random pools to keep large groups "qualified" for covered service, when they are unlikely to be called upon. Instead, carriers should plan to "qualify" only a limited number of personnel who are the most likely to be needed to perform covered service.

9.5.3.3 ***Determine that the carrier is updating its pools routinely.***

As a general rule, pools should be updated at least monthly with a changing workforce or operation, or at least quarterly for employers with a generally stable operation. Most carriers (large and small) are expected to update their pools as changes occur (monthly or more often).

9.5.3.4 ***Determine that the carrier is maintaining copies of its random pools for at least two years after they are used for selection.***

These records should be in hard copy and produced contemporaneously to when they were in use.

9.6 RANDOM SELECTIONS

9.6.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier employs a method of selection which is free from apparent bias and cannot be controlled or manipulated by the carrier or its representatives to either target or exclude any employee or operational unit.

This area receives a significant amount of FRA attention, both as a major focus in a comprehensive audit and also as a major target of employee and union complaints.

9.6.2 Records Required. The employer should be able to provide a detailed written description of the method of selection. If a computer program is employed, the description should include information on how pool entries are inputed or modified, detail on the computer program being employed (whether proprietary or off-the-shelf), how the program operates on the pool, and how the selections are transmitted to the employer. Printouts of each set of selections during the audit timeframe should be obtained by the inspector.

9.6.3 The Selection Data Base. ***Determine that every entry in a pool (individual employee, job assignment, or operational unit) has an equal chance of selection in each selection period.***

9.6.3.1 ***Assess whether anybody still actively performing covered service was deleted from the selections without just cause.***

Once a random selection has been made, the entry should be tested. After selection, it is generally too late to ignore pool entries or delete a selection. Acceptable reasons for deletion include the individual no longer being employed, documented long-term illness, the individual no longer has any opportunity to perform covered service, or the individual has not performed covered service in previous designated time period and is unlikely to do so in the upcoming period.

9.6.3.2 ***Assess whether there were any selections made without replacement.***

An individual or pool entry cannot be dropped from a pool or eliminated as a selection because they were previously tested.

9.6.3.3 ***Assess whether there were any selection weightings which would increase or decrease the chance of an employee being selected.***

No part of the selection process may increase or decrease the likelihood that any individual pool entry is selected.

9.6.4 <u>The Selection Method</u>. ***Determine that the carrier employs an acceptable method of selection which meets FRA standards.***

9.6.4.1 ***Assess whether there is any evidence that the carrier attempts several selection runs in a selection procedure in order to ensure the absence or presence of any individual, job, or operating unit.***

9.6.4.2 ***Assess whether the carrier employs an acceptable method of random selection.***

The following methods are examples of selection programs that are acceptable to FRA:

a. Computer programs which randomly select entries from an employee list without apparent bias. The specific selection criteria used by the computer must be extensively detailed in writing, and each computer draw must be retained as a record for a minimum of two years.

b. Manual selection from a list of employees using a random number table or equivalent. The specific criteria used to select from the table must be documented in writing, including detail on how the initial starting point in the table was determined. Each draw, as well as a copy of the table portion used, must be retained as a record for a minimum of two years.

Some discretion may be allowed by FRA regarding whether to apply a sanction if the employer has used an alternate procedure, method, or selection strategy not described here as long as it is a clear good faith effort to comply with the intent and the letter of the regulation or the guidance provided. Regardless, the method must have been previously approved by FRA in the carrier's random plan. Manual selection using a name or social security number drawn out of a hat (or equivalent) is not currently an acceptable selection method to meet FRA requirements.

9.6.4.3 ***Determine that adequate records are being retained by the carrier to ensure that the carrier is complying with the intent and the letter of the regulation.***

This should include, but not be limited to, computer printouts, rough notes, memoranda for the record (MFRs), etc.

9.6.5 Selection Rates. ***Determine that selections are being made in a manner which supports a reasonable distribution of tests throughout the year, will allow compliance with the published FRA test rate requirements, and be responsive to an employer's changing workforce.***

9.6.5.1 ***Assess whether random selections are being made contemporarily enough to the collection period to ensure an up-to-date pool .***

There is an expectation by FRA that collections will be evenly distributed throughout the year. It is preferred that for most carriers, a separate selection process be conducted every month to ensure that the pools are up to date. Unless a carrier's workforce and/or train operations are extraordinarily stable, quarterly selections from their pools would not be permissible if it allowed a predictable influx of new workers to avoid the deterrent effect of random testing for up to three months.

9.6.5.2 ***If a testing pool is so small that it does not allow testing each selection period, assess whether the carrier has in place a mechanism to randomly determine which selection period will have selections and which will not.***

The specific criteria used to make the determination should be detailed in writing in the carrier's Plan, and the determination must be retained as a record for a minimum of two years.

9.6.5.3 ***Assess how the carrier is determining whether a selection is to be tested for drugs, for alcohol, or for both.***

If required testing rates are different (i.e., 50% for drugs and 25% for alcohol), it is permissible to select a single list of employees from a pool and designate a proportion for both drug and alcohol testing and a proportion for either alcohol or drug testing only. The specific criteria used to make this determination must be detailed in writing in the carrier's Plan, and the master selection list with both sub-groups clearly identified must be retained as a record for a minimum of two years.

9.6.5.4 ***Assess whether the carrier is monitoring significant changes in its workforce in order to ensure that an appropriate number of tests will be conducted each year.***

The regulation permits a single annualized assessment of the number of covered service employees for purposes of calculating the number of random tests required. However, if the employer's basic covered service workforce is unstable with either predictable or unpredictable changes occurring, the carrier's Plan should allow a more fluid ability to comply with the intent of the regulation.

In general, changes of greater than 10% in a quarter should result in a recalculation of total FRA tests required.

9.7 RANDOM PROGRAM IMPLEMENTATION

9.7.1 Inspection Goal. The goal for inspecting this element is to determine whether, within reason, the carrier is testing all of its random selections appropriately, whether collections are distributed throughout the duty day and work year in a manner which contributes to the deterrent effect of the program, and whether collections can be controlled or manipulated by carrier field personnel to target or exclude any employee or operational unit.

9.7.2 Records Required. The carrier should be able to provide specific data on geographic and job-craft distributions of its covered service personnel. Printouts of all selections during the audit timeframe, including information on each selection's craft, job assignment, and job location may be important for the inspector to review. Printouts of all random collections conducted in the audit timeframe, again including information on each tested individual's craft, job assignment, and job location should be obtained. Records which demonstrate the reason for every time a selection was not collected are essential.

9.7.3 Random Collections.

9.7.3.1 *Assess whether the carrier has tested sufficient covered service employees to comply with the random testing rates for drug and alcohol testing required by FRA.*

This assessment is to be made based on FRA's determination of the number of covered service personnel who are to be subject to testing during a one year audit timeframe. Any specimen from a completed collection with an acceptable verified result (i.e., positive, negative, adulterated, substituted, or unsuitable for testing) can be counted towards meeting the FRA's rate requirement. A specimen rejected because of a procedural or documentation error at the collection site, shy bladder, or a donor refusal may also be counted towards the rate requirement.

When a selected pool entry cannot be collected in its entirety (i.e., one or more members of a train crew have expired hours of service), the collections already successfully completed are still to be counted as valid tests.

9.7.3.2 ***Assess whether collections appear to be unpredictably distributed throughout the designated testing period, covering all operating days (including Saturdays, Sundays, and holidays) and shifts (up to a 24-hour operations clock).***

There is no expectation that weekday/weekend/holiday, off-hours, or shift collection distributions be equal, but there has to be sufficient testing in all categories to establish deterrence throughout the carrier's system. Comparisons between selections and actual collections should be made, and if discrepant by over 20% in any time period, day of the week, or location, should be investigated.

9.7.3.3 ***Assess whether collections appear to be unpredictably distributed throughout the carrier's geographic system, covering both urban and rural locations.***

Generally, random selections should generally mirror carrier operations. Similarly, test distributions should also generally mirror carrier operations. Special attention should be placed on locations where there has been an overabundance or underabundance of tests noted in an operationally intense area, a particular geographic location, or a craft.

9.7.3.4 ***Assess whether collections are unpredictable within a work shift.***

Some proportion of collections must be conducted at the beginning and end of a shift. If possible, some testing in the middle of a shift should also occur. There is no expectation the "within-shift" collection distributions be equal, but sufficient testing must have been conducted to provide a deterrence throughout an employee's work day. For most carrier train operations, the majority of tests will occur at either the beginning or at the end of the work shift. This is permissible as long as at least 10% of the alcohol collections occur at the opposite end of the shift.

9.7.3.5 ***Assess whether the carrier allows field supervisory and management personnel discretion with collection dates or collection times which could result in a selective choice by a field supervisor on who was actually collected.***

If a test timeframe or some other allowance is permitted in a carrier's program, a manager or supervisor with knowledge of personnel assignments may not be permitted any discretion in selecting who is to be collected. In all cases, the carrier must be able to demonstrate to FRA that the person, job, or operating unit selected was the one actually collected.

9.7.3.6 ***Assess whether the carrier can provide written reasons for each "no-test" situation, explaining why a particular selection was not collected, with records to be maintained for two years.***

In general, every selection should be collected, unless there is an acceptable reason. Acceptable explanations to FRA are a critical safety concern, an unforeseen or unpredictable adverse impact to operations, or employee illness or vacation. Unacceptable reasons include carrier convenience, collector or supervisor unavailability, and expirations of hours of service. A 10% "no-test" rate or greater is considered unsatisfactory. Special emphasis should be placed by inspectors on assessing the "no-test" rate for high priority operations, including premier money-making trains, local freights, etc., and trains or covered service assignments working at unusual times or difficult locations.

9.7.3.7 ***Assess whether the carrier's practice of notifying employees of a random test gives too much advance warning of the collection.***

Employees must not be given an opportunity to obtain false samples or contaminating products, or to avoid the collection because the carrier's program gives too much notice and allows the employee to go unsupervised. The recommended practice is for carriers to notify an employee of their selection and escort them directly to the collection site. Selected employees must not be given an opportunity to "mark off" after being notified but awaiting collection.

9.7.3.8 ***Assess whether the carrier can provide an adequate auditable record on the implementation of its FRA random program.***

Records which demonstrate compliance with the audit elements described in this section are essential, and the carrier must be capable of documenting audit elements and providing complete systems which manage supporting records. Inadequate record systems should be considered as noncompliance by the carrier.

9.7.4 **Removal From Covered Service.** ***Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified positive.***

The carrier must have a procedure in place that facilitates the timely notification and removal of covered service employees once a verified positive report is made by the MRO based on a random test. The carrier must relieve a positive train crewmember or other covered service employee as soon as practical, but the procedure employed may reasonably accommodate carrier operations. Times for relieving a train crewmember can be at the beginning or end of a shift, or at the next routine train stop where suitable relief is available, whichever is sooner. The positive employee must be removed from covered service in a way that maintains the positive employee's right to privacy with other employees within a reasonable need to know basis.

Random Testing Summary Checklist

I. The Random Testing Plan [9.4]

A. *Determine that the carrier has a FRA-approved drug and an approved alcohol Random Plan.* [9.4.3.1]

B. *Determine that Plan amendments are being submitted properly for FRA approval.* [9.4.3.2]

C. *Determine that the Plan is complete and up-to-date on its face.* [9.4.3.3]

II. The Random Testing Pools [9.5]

A. *Determine that each FRA random pool employed by the carrier for accurately and completely includes or encompasses all covered service personnel who should be in that pool.* [9.5.3.1]

B. *Determine that carrier pools do not mix personnel regularly performing covered service with personnel who provide "de minimus" service.* [9.5.3.2]

C. *Determine that the carrier is updating its pools routinely.* [9.5.3.3]

D. *Determine that the carrier is maintaining copies of its random pools for at least two years after they are used for selection.* [9.5.3.4]

III. Random Selections [9.6]

A. **The Selection Data Base.** *Determine that every entry in a pool (individual, job assignment, or operational unit) has an equal chance of selection in each selection period.* [9.6.3]

1. *Assess whether anybody still actively performing covered service was deleted from the selections without just cause.* [9.6.3.1]

2. *Assess whether there were any selections made without replacement.* [9.6.3.2]

3. *Assess whether there were any selection weightings which would increase or decrease the chance of an employee being selected.* [9.6.3.3]

Random Testing Summary Checklist

B. <u>The Selection Method</u>. *Determine that the carrier employs an acceptable method of selection which meets FRA standards.* [9.6.4]

1. *Assess whether there is any evidence that the carrier attempts several selection runs in a selection procedure in order to ensure the absence or presence of any individual, job, or operating unit.* [9.6.4.1]

2. *Assess whether the carrier employs an acceptable method of random selection.* [9.6.4.2]

3. *Determine that adequate records are being retained by the carrier to ensure that the carrier is complying with the intent and the letter of the regulation.* [9.6.4.3]

C. <u>Selection Rates</u>. *Determine that selections are being made in a manner which supports a reasonable distribution of tests throughout the year, will allow compliance with the published FRA test rate requirement, and be responsive to an employer's changing workforce.* [9.6.5]

1. *Assess whether random selections are being made contemporarily enough to the collection period to ensure an up-to-date pool.* [9.6.5.1]

2. *If a testing pool is so small that it does not allow testing each selection period, assess whether the carrier has in place a mechanism to randomly determine which selection period will have selections and which will not.* [9.6.5.2]

3. *Assess how the carrier is determining whether a selection is to be tested for drugs, for alcohol, or for both.* [9.6.5.3]

4. *Assess whether the carrier is monitoring significant changes in its workforce in order to ensure that an appropriate number of tests will be conducted each year.* [9.6.5.4]

Random Testing Summary Checklist

IV. Random Program Implementation [9.7]

A. Random Collections. [9.7.3]

1. *Assess whether the carrier has tested sufficient covered service employees to comply with the random testing rates for drug and alcohol testing required by FRA for the audit timeframe.* [9.7.3.1]

2. *Assess whether collections appear to be unpredictably distributed throughout the designated testing period, covering all operating days (including Saturdays, Sundays, and holidays) and shifts (up to a 24-hour operations clock).* [9.7.3.2]

3. *Assess whether collections appear to be unpredictably distributed throughout the carrier's geographic system, covering both urban and rural locations.* [9.7.3.3]

4. *Assess whether collections are unpredictable within a work shift.* [9.7.3.4]

5. *Assess whether the carrier allows field supervisory and management personnel discretion with collection dates or collection times which could result in a selective choice by a field supervisor on who was actually collected.* [9.7.3.5]

6. *Assess whether the carrier can provide written reasons for each "no-test" situation, explaining why a particular selection was not collected, with records to be maintained for two years.* [9.7.3.6]

7. *Assess whether the carrier's practice of notifying employees of a random test gives too much advance warning of the collection.* [9.7.3.7]

8. *Assess whether the carrier can provide an adequate auditable record on the implementation of their FRA random program.* [9.7.3.8]

B. Removal From Covered Service. *Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified positive.* [9.7.4]

10.0

MANDATORY

POST-ACCIDENT

TESTING

10.0 MANDATORY POST-ACCIDENT TESTING

10.1 OVERVIEW

FRA regulations found in 49 CFR 219.201 – 219.213 (Subpart C) describe requirements for FRA mandatory post-accident testing. This special program has been the cornerstone of FRA's drug and alcohol testing effort, and pre-dates the rest of Part 219. FRA's intent is that the agency may determine after rule-triggering train accidents or incidents whether the use of drugs or alcohol by railroad covered service employees may have caused or contributed to the severity of the event. FRA's goal for an effective carrier program is that each railroad is fully prepared to conduct testing if a rule-triggering event occurs; that the decision to test is made quickly after reasonable inquiry and a good faith judgment by on-site carrier supervisory personnel; that blood and urine collections from surviving employees are completed within four hours of the accident with the proper supplies and forms; and that blood, urine, and tissue collections from deceased employees or other railroad personnel are completed as soon as possible.

10.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Hazardous Material; Impact Accident; Independent; Medical Facility; Medical Practitioner; NTSB; Passenger Train; Railroad; Railroad Property Damage or Damage to Railroad Property; Refuse to Submit; Reportable Injury; Reporting Threshold; Supervisory Employee; Train; Train Accident; Train Incident
- 219.201 – Events for Which Testing is Required
- 219.202 – [Reserved]
- 219.203 – Responsibilities of Railroads and Employees
- 219.204 – [Reserved]
- 219.205 – Sample Collection and Handling
- 219.206 – FRA Access to Breath Test Results
- 219.207 – Fatality
- 219.208 – [Reserved]
- 219.209 – Reports of Tests and Refusals
- 219.210 – [Reserved]
- 219.211 – Analysis and Follow-Up

- 219.212 – [Reserved]
- 219.213 – Unlawful Refusal; Consequences
- Appendix C to Part 219 – Post-Accident Testing Sample Collection

10.3 INSPECTION OR AUDIT FOCUS

There are four major elements in a carrier's mandatory post-accident testing program which must be assessed:

- Carrier Preparation
- The Decision to Test
- Collections From Surviving Employees
- Collections From Fatally Injured Employees

10.4 CARRIER PREPARATION

10.4.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is properly prepared to conduct mandatory post-accident collections on any portion of its system at any time of the day or night. This includes assessing whether the carrier has access to proper collection facilities which fully cover the carrier's catchment area and whether all its supervisors who may be responsible for making that determination are properly trained in FRA post-accident determinations. Supervisors must be capable of making the proper regulatory decisions on whether to test and whom to test when confronted with a possible rule triggering event.

10.4.2 Records Required. The carrier should be able to provide specific data on the geographic distribution of post-accident collection sites and FRA post-accident toxicology kits throughout its system. Copies of supervisor and management training records are also important for the inspector to review. Interviews with field supervisors and headquarters personnel are likely to be required.

10.4.3 Collections.

10.4.3.1 *Determine that the carrier has an adequate supply of FRA mandatory post-accident toxicology boxes to support its entire system.*

Generally, carriers should be able to get at least two FRA toxicology boxes to any of its designated post-accident collection sites within two hours of an accident. In an emergency, additional boxes can often be obtained from local FRA inspectors and local railroads, but this should not be considered by the carrier to solve its distribution obligation. A periodic inventory of toxicology boxes by location is strongly recommended at least once a year.

10.4.3.2 *Determine that the carrier's toxicology box supply has been kept up to date and includes an accurate address for the designated FRA post-accident laboratory and unexpired blood tubes in each kit.*

The carrier should periodically ensure that each FRA post-accident toxicology box it maintains is complete, and has up-to-date supplies.

10.4.3.3 *Determine whether the carrier maintains an up-to-date list of collection locations which adequately ensures that post-accident collections can occur seven days a week/24 hours a day throughout the carrier's system.*

Carriers are responsible for ensuring that they have active access to sufficient contracted independent collection facilities to support post-accident testing throughout its system. Arrangements with collection sites must be made in advance, so that carrier personnel are aware of exactly where to go when they have a rule triggering event. It is hoped that wherever possible, satisfactory collection services are to be available within two hours of any potential accident site on the carrier's system.

Collectors and collection facilities must be independent of the carrier. That is, no employee of the railroad may collect specimens, nor may specimens be collected on carrier owned or controlled property.

10.4.3.4 ***Determine whether the carrier has properly trained all its field supervisory personnel responsible for the test decision in post-accident qualifying events and the post-accident collection procedures.***

Carriers must ensure that all field supervisors who may be responsible for the testing determination are properly trained (at least one hour) in all aspects of the Federal post-accident requirements. Successful completion of this training for each individual must be documented in the carrier's records. The training content itself must be auditable and should include at least a clear differentiation of the qualifying events; a description of who is to be tested (and who may not be tested) in each of the qualifying events; the exceptions to testing; a discussion on the authority of outsiders (local police officers, NTSB, etc.); a review of what constitutes a good faith determination; the importance and timeliness of sample collection; the circumstances under which an employee could be recalled for testing; and program collection and sample transfer procedures.

When queried, field supervisory personnel should be able to describe FRA post-accident requirements, and/or must be able to immediately access carrier reference documents on post-accident determinations and collections which are to be closely available to the supervisor during an accident or incident.

10.5 THE POST-ACCIDENT TESTING DECISION

10.5.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is making the correct testing decisions on potential post-accident qualifying events.

10.5.2 Records Required. The carrier should be able to produce copies of its monthly FRA F6180.55, F6180.55a, and F6180.54 reports made to FRA headquarters during the audit timeframe. These reports should cover all carrier reportable accidents and incidents. A summary of these reports can also be obtained from FRA's Accident Reports Section. Copies of Subpart C testing events reported to FRA (qualifiers and cancellations) can be obtained from FRA's Drug and Alcohol Program Manager. Interviews with carrier field supervisors and program management staff may also be required to discuss specific cases.

10.5.3 Determinations to Conduct Post-Accident Testing.

10.5.3.1 ***Determine whether each Subpart C testing determination was made by on-site supervisory personnel, and in a timely manner.***

10.5.3.2 ***Determine whether each Subpart C test actually conducted in the audit timeframe was a proven qualifying event under the regulations.***

10.5.3.3 ***Determine that employees actually tested and personnel excluded from testing were properly decided.***

10.5.3.4 ***Determine whether any incorrect testing determinations were made under Subpart C requirements and assess the reasons for the inappropriate decision.***

Determinations on Subpart C testing must be made by an on-site carrier supervisor properly trained in FRA post-accident requirements. The supervisor must have had no direct involvement in the accident or incident. The supervisor is responsible for making a good faith determination with due diligence on whether the event was a rule-triggering event, based on a reasonable inquiry into the relevant facts that could be uncovered at the time of the accident/incident. The supervisor may consult with other carrier personnel, both technical and managerial, but is to be ultimately responsible for the final decision on whether the event is a Subpart C qualifier.

There may be no unnecessary delay in making the determination of whether the accident or incident was a qualifying event, in deciding which employees must be tested (including employees at other locations), or in sending surviving employees to the contracted collection site. Time is of the essence, and both speed in decision-making and an expeditious execution of the decision are among the most essential elements in the post-accident program.

In making a proper determination, the supervisor must consider all FRA requirements, including:

- If the event fell within one of the testing exclusions (highway/rail grade crossing, natural causes, or vandalism)

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- Depending on the type of test, if any employees are allowed to be excluded from testing because there was clear non-involvement in the cause and/or severity of the event

- If any covered employees not part of the train crew need also be tested

- If any covered employees required to be tested were already released from duty, and the circumstances (if any) under which they could be recalled

After investigating the circumstances and consequences of each accident or injury/fatality reported by the carrier, it should be determined whether the carrier made accurate and timely decisions on whether to test and who to test under FRA regulations.

Employees subject to possible testing should have been retained in a duty status until the testing decision had been made and executed. Once released, an employee cannot be recalled for testing unless:

a) The employee went off duty normally prior to being contacted by a supervisor and instructed to remain; and

b) The railroad's investigation indicated a clear probability that the employee played a role in the cause or severity of the accident/incident; and

c) The accident/incident occurred on the employee's duty tour.

It is essential that specimens be collected from the proper personnel after every rule-triggering event. Personnel may be required to exceed hours of service limitations while the test determination and specimen collections are being completed. Excess hours of service must be reported, but FRA will likely use its prosecutorial discretion and not cite the carrier as long as the carrier proceeded with reasonable due diligence.

There are circumstances where an incorrect Subpart C determination may have been made, but the on-site supervisor demonstrated commendable due diligence, common sense, and good faith given the available facts and the need to make a timely decision required by the Rule. Such an error may often not warrant remedial or administrative action by FRA. However, poor or incorrect decisions due to

ignorance of the testing events or Subpart C exclusions, personal or professional negligence, or because the supervisor failed to follow standard carrier procedures is unacceptable and will invoke a sanction by FRA.

10.6 COLLECTIONS FROM SURVIVING EMPLOYEES

10.6.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is able to transport employees to post-accident collection sites in a timely manner, whether the collection sites appear to be performing their duties and responsibilities correctly, and whether specimens are being transported to the FRA post-accident laboratory within 24 hours of the accident as required by the Rule.

10.6.2 Records Required. Copies of all FRA Forms F6180.73s and F6180.74s for qualifiers and cancellations should be reviewed and compared with other laboratory and carrier records which document the collection and specimen transfer. Interviews with carrier personnel and collection site personnel may be required.

10.6.3 Surviving Covered Employee Collections.

10.6.3.1 *Determine whether specimens on surviving covered employees are being obtained within four hours of a qualifying event, and if not, establish whether the reasons for the delay are acceptable.*

Carriers need to ensure that whenever possible specimens are collected within four hours of a qualifying accident or incident. There should be no unnecessary delays in relieving train crewmembers from the accident scene. Crewmembers and other covered employees designated for testing should be transported to the collection site as soon as the accident scene is stabilized and crew and passenger safety has been established.

The carrier is required to maintain documentation when a collection occurs more than four hours after a rule-triggering event. Any delays beyond four hours in obtaining specimens should be investigated to determine if they were reasonable and not due to factors within the carrier's control (i.e., waiting for a breath alcohol test to be conducted, failure to relieve crewmembers from the accident scene without justification, designated collection site too far away when a closer one could have been previously arranged, confusion at the collection site, etc.)

10.6.3.2 ***Determine whether collection sites are qualified to collect urine and blood specimens in accordance with FRA post-accident procedures, are performing collections in accordance with the regulations, are properly documenting chain-of-custody, and are facilitating the transportation of specimens to the FRA post-accident laboratory to ensure arrival within 24 hours.***

Post-accident collections must be conducted at an independent medical facility capable of the proper care and treatment necessary to protect the health and medical safety of carrier employees involved in the accident or incident. The facility may not be on the carrier property or property under direct carrier control (i.e., cannot be presently located as part of the carrier's medical department).

Specimens must be collected by qualified medical personnel not under the carrier's direct control (i.e., may not be carrier employees). Collectors must be independent contractors in relation to the carrier, but not necessarily employees of the independent medical facility (although it is strongly recommended).

A carrier-hired contractor collection service may perform collections at another independent medical facility, as long as the contractor is otherwise medically qualified under the regulation and medical emergencies can be immediately handled.

Even though they may not be there to actually collect specimens, a contractor collection service may also be retained by the carrier to provide oversight to the independent medical facility's collector personnel, advising them of proper post-accident collection procedures. This is permissible as long as they do not physically interfere with the collectors of record. This does not waive the employer's responsibility to have a railroad official present, who has ultimate authority for the collection process.

The carrier is responsible for ensuring that the collectors are provided their copies of the instructions found in the post-accident toxicology box. The railroad official accompanying the employees to be tested should be knowledgeable of FRA's collection requirements.

Specimen collections must be properly documented on FRA's post-accident collection forms (FRA F6180.73 and FRA F6180.74). The F6180.73 is an accident summary form to be filled out by the railroad representative accompanying the employees to the collection site. Each individual chain-of-custody collection form (F6180.74) must be properly completed by the donor and the

collector(s). The Form 74 fully documents both blood and urine collections up through the point of specimen shipment, and contains all collector, observer, and donor signatures. An example of a properly completed F6180.73 form can be found at Tab 3. An example of a properly filled out F6180.74 using two collectors working in tandem can also be found at Tab 3.

Potentially fatal flaws in a collection include the absence of one or more collector or donor signatures; a discrepancy between the identification number on the form and on the specimens themselves; specimen seals absent or breached; and the appearance on the chain-of-custody form of names or signatures of individuals who are not the collector, observer, or donor. Errors in documentation can often be recovered through the use of signed statements, with the exception of those where the proper identify of the specimen cannot be absolutely determined.

It is essential that both blood and urine samples are collected from each donor, preferably blood first to avoid any potential collection delay due to shy bladder. A single collector can obtain both blood and urine specimens, or multiple collectors can be employed (i.e., one collecting the blood and a second collecting urine).

Each collector can only collect one sample from one donor at a time until the particular specimen is labeled, sealed, and documented on the F6180.74. It is permissible for a single collector to collect blood samples from the entire donor group, one at a time, then return and collect urine specimens one at a time from the same donor group.

Neither a railroad representative nor a FRA inspector may physically participate in any way in the collection of specimens (including as an observer in a direct observation urine collection). Both may advise collection personnel on proper FRA procedures, but may not materially interfere with the collector and his/her performance of duties.

The carrier is responsible for ensuring that the specimens are transported to the FRA's post-accident laboratory to arrive within 24 hours. The selected courier service agent, arriving to take possession of the sealed post-accident toxicology box for shipment, does not personally sign the chain-of-custody form. Documentation of specimen transfer is only to be made on the F6180.74 as to the identity of the specific courier service (i.e., FedEx, Airborne, UPS, etc.). Documentation of the identity of the specific courier agent is sufficient on the courier service's shipping bill.

A representative of the carrier may take possession of the sealed toxicology box for purposes of delivering it to an overnight courier, an airport, or an airline. In such circumstance, the handling of the transport box by the railroad representative need not be documented on the chain-of-custody form. However, the carrier should be knowledgeable of that occurrence, and be prepared to identify any supervisors involved and the specific reasons that the collection site would or could not ship the box.

10.6.3.3 ***Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified positive.***

Carriers may not hold employees out of covered service pending the laboratory results of a post-accident test using Federal authority, but holding employees out of service under their own company or medical department authorization based on the post-accident event is not prohibited.

Carrier personnel may contact the FRA's Drug and Alcohol Program Manager or his designee about the progress of the laboratory in the testing of post-accident specimens, but are not to directly contact laboratory personnel before the release of the final reports other than to ensure that the toxicology box arrived.

Test results from Subpart C post-accident events will be sent by the FRA contract post-accident laboratory to the employee and to the carrier's MRO. The MRO has no role with fatalities, but performs his/her duties in accordance with DOT requirements on results from surviving employees.

The carrier must have a procedure in place that facilitates the timely notification and removal of covered service employees once a verified positive report is made by the MRO. The carrier must relieve a positive train crewmember or other covered service employee as soon as practical, but the procedure employed may reasonably accommodate carrier operations. Times for relieving a train crewmember can be at the beginning or end of a shift, or at the next routine train stop where suitable relief is available, whichever is sooner. The employee testing positive must be removed from covered service in a way that maintains the employee's right to privacy with other employees within a reasonable need to know basis.

10.7 COLLECTIONS FROM FATALLY INJURED EMPLOYEES

10.7.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier has exercised due diligence in ensuring that required specimens from fatally injured employees are harvested by competent authority and transported to the FRA's post-accident laboratory in as expeditious a manner as possible.

10.7.2 Records Required. Copies of relevant FRA Forms F6180.73 and 74s may be necessary to be reviewed. Interviews with carrier personnel and medical examiner/coroner/mortuary personnel may be necessary.

10.7.3 Collections From Fatally Injured Employees. ***Determine whether the carrier has exercised due diligence in ensuring that the required specimens (blood, urine, and tissue) are collected from fatally injured employees and that the specimens are transported to the FRA post-accident laboratory as soon as possible.***

Carriers do not need to ensure that specimens from fatally injured employees are harvested within any specific timeframe, only that the requirement is accomplished as soon as practical. The carrier is only responsible for ensuring that the local jurisdiction (medical examiner, coroner, etc.) is made aware of the Federal requirements and involves the FRA if it becomes a jurisdictional issue. Under Federal law, no consent to take samples is required from the deceased's family.

It is FRA's opinion that chain-of-custody issues are not as significant with a fatally injured employee. Therefore the carrier has no obligation to accompany the body to the medical examiner, coroner, or mortuary. In addition, there is no circumstance where any carrier representative must be present at the harvesting of the specimens. It is essential, however, that the set of instructions for the collection of post-mortem specimens be presented to the authority collecting the samples.

POST-ACCIDENT

Depending on availability, all the following specimens are important to be obtained (in order of significance) at autopsy and before embalming:

- blood
- urine
- vitreous
- liver
- bile
- brain
- kidney

Other specimens (i.e., spleen, lung) may also be of use but are not as critical to obtain unless many of the other sample types are not available.

At least 20 mL of blood should be obtained from an intact femoral vein or artery or from peripheral vessels and an intact heart. If no uncontaminated blood is available, bloody fluid or clots may be acceptable but they should not be labeled as blood. As much urine as possible (up to 100 mL) would be valuable. All vitreous fluid available from any intact eyes and 50-100 grams of the other specimens should be obtained if possible.

Although FRA toxicology boxes are not specifically designed to collect post-mortem specimens, samples may be transferred to the FRA laboratory using the current post-accident toxicology kits and transport box. If the agency harvesting the specimens has better containers to house the specimens, they may use their supplies. The carrier need not be directly involved in the transportation of samples, but must ensure that the local jurisdiction transfers the specimens to the FRA post-accident laboratory as soon as possible. It is permissible for the agency harvesting specimens to delay transport to properly prepare the samples for shipment (i.e. freezing tissues, etc.).

Post-Accident Test Summary Checklist

I. Carrier Preparation [10.4]

A. *Determine that the carrier has an adequate supply of FRA mandatory post-accident toxicology boxes to support its entire system.* [10.4.3.1]

B. *Determine that the carrier's toxicology box supply has been kept up to date and includes an accurate address for the designated FRA post-accident laboratory and unexpired blood tubes in each kit.* [10.4.3.2]

C. *Determine whether the carrier maintains an up-to-date list of collection locations which adequately ensures that post-accident collections can occur seven days a week/24 hours a day throughout the carrier's system.* [10.4.3.3]

D. *Determine whether the carrier has properly trained all its field supervisory personnel responsible for the test decision in post-accident qualifying event and the post-accident collection procedures.* [10.4.3.4]

II. The Post Accident Testing Decision [10.5]

A. *Determine whether each Subpart C testing determination was made by the on-site supervisory personnel, and in a timely manner.* [10.5.3.1]

B. *Determine whether each Subpart C test actually conducted in the audit time-frame was a proven qualifying event under the regulations.* [10.5.3.2]

C. *Determine that employees actually tested and personnel excluded from testing were properly decided.* [10.5.3.3]

D. *Determine whether any incorrect testing determinations were made under Subpart C requirements and the reasons for the inappropriate decision.* [10.5.3.4]

Post-Accident Test Summary Checklist

III. Collections From Surviving Employees [10.6]

A. *Determine whether specimens on surviving crewmembers are being obtained within four hours of a qualifying event, and if not, establish whether the reasons for the delay are acceptable.* [10.6.3.1]

B. *Determine whether collection sites are qualified to collect urine and blood specimens in accordance with FRA procedures, are performing collections in accordance with the regulations, are properly documenting chain-of-custody correctly, and are facilitating the transportation of specimens to the FRA post-accident laboratory to ensure arrival within 24 hours.* [10.6.3.2]

C. *Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified positive.* [10.6.3.3]

IV. Collections From Fatally Injured Employees [10.7]

A. *Determine whether the carrier has exercised due diligence in ensuring that the required specimens (blood, urine, and tissue) are collected from fatally injured employees and that the specimens are transported to the FRA post-accident laboratory as soon as possible.* [10.7.3]

11.0

REASONABLE

SUSPICION

REASONABLE

CAUSE

11.0 REASONABLE SUSPICION/ REASONABLE CAUSE

11.1 OVERVIEW

FRA regulations found in 49 CFR 219.300 – 219.305 (Subpart D) describe requirements and authorization for FRA reasonable suspicion and reasonable cause testing. As defined by FRA, reasonable suspicion involves a concern about the possible drug and/or alcohol impairment of an individual employee. Reasonable cause primarily involves a concern about an event, either a specified rule violation or involvement in a FRA reportable accident/incident where one or more employees' acts or omissions contributed to the cause or severity.

Reasonable suspicion is a mandatory Federal test, involves the face-to-face assessment of the employee by either one or two trained supervisors (depending on whether alcohol or drugs is suspected), and must be based on the behavior, speech, or body odors seen in that particular employee at that moment.

Federal reasonable cause testing is authorized by FRA regulations but is not required. When conducted under Federal authority, reasonable cause testing may be necessitated when there has been an accident or incident reportable under Part 225 (but does not meet Subpart C thresholds) and the employee may have played a role in its cause or severity, or there has been a violation of one of the operational rules or errors identified in 219.301. A carrier is permitted to maintain a reasonable cause test program under its own authority, which may be used either instead of, or as a complement to, Federal reasonable cause testing. A carrier is under no Federal obligation to conduct reasonable cause testing (Federal or company authority) after any particular event or to even have a reasonable cause program of either type.

Through implementation of an effective reasonable suspicion and Federal reasonable cause testing program, the carrier will be able to uncover impaired employees, and by doing so, ultimately deter use of alcohol and drugs on or just before duty. FRA's goal for an effective carrier program is that carrier supervisors have at least two hours training in reasonable suspicion and reasonable cause determinations; that carrier supervisors are able to clearly distinguish between reasonable cause testing under Federal authority and under company authority, if applicable; and that the carrier's efficiency check observations are effective in

detecting Rule G violations and act as a deterrent to drug and alcohol use by covered employees. FRA's objective is that supervisors are actively working to ensure employee compliance with alcohol and drug use prohibitions. Employees are to be treated fairly and objectively judged based on the available facts, and not on third party information or supposition.

11.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Co-Worker; Refuse to Submit; Reportable Injury; Supervisory Employee
- 219.300 – Mandatory Reasonable Suspicion Testing
- 219.301 – Testing for Reasonable Cause
- 219.302 – Prompt Sample Collection; Time Documentation
- 219.303 – Alcohol Test Procedures and Safeguards
- 219.304 – [Reserved]
- 219.305 – Urine Test Procedures and Safeguards

11.3 REASONABLE SUSPICION

11.3.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is properly conducting mandatory reasonable suspicion testing in accordance with FRA regulations. This includes assessing whether supervisors have been properly trained in reasonable suspicion determinations, and whether they are prepared to conduct testing when confronted with an employee who may be impacted by drugs and/or alcohol on the job. An evaluation should be conducted to determine whether the carrier's program has sufficient trained collectors (urine and breath) with access to appropriate supplies and qualified equipment to accomplish required testing on very short notice. In addition, it should also be assessed whether the railroad's program of operational (efficiency) tests and inspections are being conducted in a manner where a competent Rule G or reasonable suspicion determination is possible.

11.3.2 Records Required. Copies of supervisory management training records are important for the inspector to review. An assessment of records from a number of reasonable suspicion determinations would be essential. Records which document the carrier's compliance with Part 217.9 (Program of Operational Tests and Inspections) will also be necessary to review. Extensive interviews with field supervisors and headquarters personnel should be required.

11.3.3 Reasonable Suspicion.

11.3.3.1 *Determine that all supervisory personnel who may be responsible for making a reasonable suspicion determination have the proper training.*

In general, FRA expects that carriers are responsible for ensuring that all of its field supervisors who may be assigned to make a reasonable suspicion determination on covered employees have been properly trained (at least two hours) in all aspects of the Federal requirements. Although not directly required by the rule, FRA expects that supervisors responsible for this determination should have received their original training or a refresher in the past two years. Successful completion of this training for each supervisor must be documented in the carrier's records. The training content itself should be auditable and should include both a clear description of the signs and symptoms which suggest employee drug and alcohol use, but also the procedures necessary to confront a covered employee who may be impaired, supervisor do's and don'ts, and proper documentation elements.

11.3.3.2 *Determine that supervisory personnel responsible for the reasonable suspicion determination are fully knowledgeable of their duties and responsibilities when they suspect a covered employee of being impaired by drugs and/or alcohol.*

Field supervisory personnel should be able to describe FRA reasonable suspicion requirements, or must be able to immediately access carrier reference documents on reasonable suspicion determinations which are to be closely available to the supervisor at all times.

Supervisors should use a variety of means of personal contact and communications to assess employees for drug and/or alcohol impairment. One of the more important mechanisms in the opinion of the FRA is the Part 217 efficiency/ operational test mechanism provided for by the Rule. FRA expects trained supervisors to use the efficiency check in a manner which ensures a regular face-to-face evaluation of each covered employee, to the degree that at least one of the categories which suggest impairment (behavior, speech, or employee body odors) can be assessed during each contact counted on the FRA yearly Management Information System (MIS) report.

REASONABLE SUSPICION

Supervisors must not be afraid to confront potentially impaired covered employees, and must always be available to other supervisors who require a second opinion on an employee they are confronting. With reasonable suspicion, supervisors need not always be right, but instead must have made a good faith determination to test based on the available facts (which they must be able to articulate). Carriers must fully support the use of reasonable suspicion as an important tool to help ensure rail safety.

11.3.3.3 *Assess reasonable suspicion cases in the audit timeframe to ensure that both supervisor and carrier documentation of the incident indicates compliance with FRA regulations.*

In reasonable suspicion, the trained supervisor must base their determination on specific, contemporaneous, articulable observations concerning the appearance, behavior, speed, or body odors of the covered employee. For drugs, a second supervisor's concurrence with the original supervisor's assessment is necessary. The second supervisor need not be trained or even present for the determination (a telephone consultation or similar means of communication is permitted).

Under no circumstances can a supervisor use information obtained from another source or a third party to require a reasonable suspicion test. The entire basis of the determination must be what the supervisor observes personally.

Carriers and supervisors are expected to maintain documentation which supports each reasonable suspicion determination, including the date and time of the incident, observed behavior, evidence of the concurrence of a second trained supervisor (drugs only), name of witnesses (and statements if available), and final disposition of the case. A breath specimen for alcohol and/or a urine specimen for drugs is required, but other samples (i.e., blood) may not be obtained. Hours of service limitations are suspended for a reasonable suspicion collection once the decision is made. However, the excess service must be reported and FRA will likely use its prosecutorial discretion not to apply a sanction if the carrier has used due diligence to complete the collection as soon as possible. Shy bladder rules, of course, still apply.

11.3.3.4 ***Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified reasonable suspicion positive.***

There is no FRA requirement which mandates whether an employee may be retained in covered service pending the carrier receiving the results of the reasonable suspicion test. It is expected, however, that most carriers will suspend a person from covered service under their own authority in such a circumstance based on the reasonable suspicion of impaired performance. If the carrier retains the employee in covered service, the carrier must have a procedure in place that facilitates the timely notification and removal of the employee once a verified positive report is made by the MRO. A positive train crewmember or other covered service employee must be relieved as soon as practical, but the method employed should reasonably accommodate carrier operations. Acceptable times for relieving a crewmember can be at the beginning or end of a shift, or at the next routine train stop where suitable relief is available, whichever is sooner. The positive employee must be removed from covered service in a way that maintains the employee's right to privacy with other employees, but within a reasonable need to know basis.

11.4 REASONABLE CAUSE

11.4.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is conducting any reasonable cause testing; whether the testing is under Federal authority or company policy, or both; whether the testing authority is being properly represented to the employee; and whether any testing performed under Federal authority is being properly conducted in accordance with FRA regulations.

11.4.2 Records Required. Copies of the carrier's Part 217 Operational Tests and Inspections Program reports and related information from the carrier's MIS report covering employee drug and alcohol observations (Section C) are important for inspector review. Additional information from the carrier providing detail on Federal reasonable cause tests would also be important. Interviews with field supervisory personnel would be essential.

11.4.3 Reasonable Cause.

11.4.3.1 *Determine whether the carrier is conducting Federal reasonable cause testing, company policy testing, or a blend of both. If both, determine the circumstances which would cause a supervisor to choose between Federal or company authority.*

Carriers relying on their own company authority exclusively are not constrained by Federal guidelines, and may test a broader range of employees with less restrictive thresholds than is permitted under FRA regulations. FRA would be interested in such a company reasonable cause program only to determine that the appearance of Federal authority is not being given in any program documents or policy guidelines and Federal chain-of-custody forms are not being used. FRA should also ensure that the carrier is not applying Federal sanctions based on the results of a positive company test. This especially includes decertification of engineers.

11.4.3.2 *If both Federal and company authority is being used, determine if field supervisory personnel are capable of distinguishing between the two programs, and can clearly articulate the threshold requirements for the Federal reasonable cause program.*

If the carrier is blending both types of reasonable cause testing, all company policies, procedures, and published guidelines should clearly differentiate on how and when each program is to be applied. In all circumstances, it must always be made known to the employee under whose authority they are being tested. At the least, use of Federal and non-Federal chain-of-custody forms provides a minimum notification to the employee.

Supervisors must be clear on when Federal or company authority is being utilized when conducting a test, and be able to distinguish when an accident or incident automatically reaches the FRA mandatory post-accident testing threshold. Such information should be made part of a formal carrier training program.

11.4.3.3 ***If Federal authority is being used, assess Federal reasonable cause cases in the audit timeframe to ensure that both supervisor and carrier documentation of the event indicates compliance with FRA regulations.***

If Federal authority is being utilized for a reasonable cause determination, all applicable portions of Part 219 and Part 40 apply. A breath specimen for alcohol and/or a urine specimen for drugs is required, but other types of samples (i.e., blood) may not be obtained. Federal chain-of-custody forms must be utilized. Hours of service limitations on collections must not stop the collection, but the carrier must report the excess service to FRA. FRA will likely use its prosecutorial discretion not to apply a sanction if the carrier used due diligence to complete the collection. Shy bladder rules, of course, still apply.

Testing using Federal authority may be required only if the following Part 219 provisions are met:

- a covered service employee is involved in a rail equipment accident or incident reportable under Part 225 but which does not meet Subpart C thresholds, and the supervisor's investigation suggests that one or more employees' acts or omissions could have caused or contributed to the severity of the event, or

- a covered service employee is involved in one of the rule violations or errors identified in 219.301.

If the Federal criteria for a rule violation is met, there is no requirement for an acts or omissions determination to be made. The rule violation provides "per se" reasonable cause for a Federal drug and/or alcohol test.

For reportable accident/incidents, Federal reasonable cause testing must be separately determined for each individual employee. When the employee could not have had any responsibility for the event, they may not be tested. In each instance where the carrier intends to use an accident/incident event to initiate a Federal test, the supervisor must make a reasonable inquiry and develop facts to support whether each involved covered service employee contributed to the occurrence or severity of the event. While not required by the rule, documentation maintained by the supervisor about the circumstances of the event and the reasons for the supervisor's determination may assist in later carrier or FRA investigations.

Only the results of Federal tests are acceptable in Part 240 engineer decertification actions.

11.4.3.4 ***Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified Federal reasonable cause positive.***

There is no FRA requirement which mandates whether an employee can be retained in covered service pending the results of a Federal reasonable cause test. It is expected that many carriers will suspend a person from covered service in such a circumstance. However, if the carrier retains the employee in covered service, the carrier must have a procedure in place that facilitates the timely notification and removal of an employee once a verified positive report is made by the MRO. The carrier must relieve a positive train crewmember or other covered service employee as soon as practical, but the procedure employed may reasonably accommodate carrier operations. Acceptable times for relieving a train crewmember can be at the beginning or end of a shift, or at the next routine train stop where suitable relief is available, whichever is sooner. The positive employee must be removed from covered service in a way that maintains the employee's right to privacy with other employees, within a reasonable need to know basis.

RS/RC Test Summary Checklist

I. <u>Reasonable Suspicion</u>. [11.3.3]

A. *Determine that all supervisory personnel who may be responsible for making a reasonable suspicion determination have the proper training.* [11.3.3.1]

B. *Determine that supervisory personnel responsible for the reasonable suspicion determination are fully knowledgeable of their duties and responsibilities when they suspect a covered employee of being impaired by drugs and/or alcohol.* [11.3.3.2]

C. *Assess reasonable suspicion cases in the audit timeframe to ensure that both supervisor and carrier documentation of the incident indicates compliance with FRA regulations.* [11.3.3.3]

D. *Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified reasonable suspicion positive.* [11.3.3.4]

II. <u>Reasonable Cause</u>. [11.4.3]

A. *Determine whether the carrier is conducting Federal reasonable cause testing, company policy testing, or a blend of both. If both, determine the circumstances which would cause a supervisor to choose between Federal or company authority.* [11.4.3.1]

B. *If both Federal and company authority is being used, determine if field supervisory personnel are capable of distinguishing between the two programs, and can clearly articulate the threshold requirements for the Federal/ reasonable cause program.* [11.4.3.2]

C. *If Federal authority is being used, assess Federal reasonable cause cases in the audit timeframe to ensure that both supervisor and carrier documentation of the event indicates compliance with FRA regulations.* [11.4.3.3]

D. *Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified Federal reasonable cause positive.* [11.4.3.4]

12.0

RETURN TO COVERED SERVICE

SUBSTANCE ABUSE PROFESSIONAL

RETURN-TO-WORK

FOLLOW-UP

12.0 RETURN TO COVERED SERVICE (SAP, Return-to-Work, Follow-Up)

12.1 OVERVIEW

FRA regulations found in 49 CFR 219.104 and 219.405 outline requirements to return an employee to covered service after failing a required FRA drug or alcohol test; after any other violations of 219.101 and 219.102; after refusing a required FRA drug or alcohol test; or after completion of a co-worker report initiated program (as outlined in 219.405). These guidelines also apply in part after completion of a voluntary referral program (as outlined in 219.403) if a SAP is used.

In order to return to covered service, personnel must be assessed by a qualified Substance Abuse Professional (SAP) and successfully complete the treatment plan (counseling, treatment, or education) established for them. Once the employer has received a recommendation for return to work from the SAP and has agreed to accept an employee back into covered duty, the employee must take and pass a Federal drug and/or alcohol return-to-work test. They must also undergo mandated Federal follow-up testing for the length of time and frequency directed by the SAP. No Federal return to work or follow-up testing is required for participants in a FRA voluntary referral program.

It is FRA's intent that carriers not return personnel to covered duty until it can be determined that the employee is now unlikely to violate the drug and alcohol prohibitions of the FRA regulation. Once returned, FRA intends the employee be monitored through follow-up testing to help ensure that they remain in compliance. With the exception of the voluntary referral program, it is FRA's goal that the carrier's Part 219 program does not return personnel to covered service until they are recommended by the SAP, have demonstrated they are currently drug and alcohol free by passing a Federal return-to-work test, and have evidenced their commitment to remain drug and/or alcohol free by passing continued unannounced follow-up tests.

12.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Refuse to Submit
- 219.104 – Responsive Action (Subpart B)
- 219.403 – Voluntary Referral Policy (Subpart E)
- 219.405 – Co-Worker Report Policy

12.3 INSPECTION GOAL

The goal for inspecting this element is to determine whether the carrier has returned covered service employees back to duty consistent with FRA requirements established by the Rule, and has made a good faith effort to monitor the employee's continued compliance through the proper application of unannounced follow-up tests.

12.4 RECORDS REQUESTED

The inspector should evaluate case records for employees returned to covered service in the audit timeframe, including letters for the carrier from the SAP; the results of the Federal return-to-work test; and the results of all Federal follow-up tests. A review of personnel and payroll records may also be required. Interviews may be necessary with the carrier's SAP. The inspector need not review SAP clinical records or notes.

12.5 THE SUBSTANCE ABUSE PROFESSIONAL (SAP)

12.5.1 *Determine that the SAPs performing the service for the carrier are fully qualified under Department of Transportation guidance.*

In order to qualify to perform SAP services, the proposed SAP must be a licensed physician (MD or DO); be a licensed or certified psychologist or social worker; be a Certified Employee Assistance Professional (CEAP); or be an addictions counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC) or the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse (ICRC). No other certifications or licenses are currently acceptable. The SAP may be an employee of the carrier, under contract to the carrier, or be completely independent from the carrier.

12.5.2 *Determine that carrier SAPs are conducting proper initial assessments of covered service employees referred to them and referring employees in accordance with the SAP guidance.*

All SAP initial assessments must be conducted face-to-face with the covered employee, and may not be conducted by telephone or by a third party. The SAP

actually interviewing the employee remains the SAP of record throughout the case and the assessment, referral, and return to work decisions may not be deferred to any other individual, even if that person is also a qualified SAP.

The SAP must have knowledge and clinical experience in the diagnosis and treatment of alcohol and other substance abuse disorders. SAP responsibilities include providing an initial clinical assessment and evaluation (determining what level of assistance is needed); developing a treatment plan; referring the employee to an appropriate treatment or education program; evaluating the employee for return to duty when they have successfully completed a sufficient proportion (or all) of the treatment plan; and establishing a follow-up testing plan.

The SAP may not refer a covered employee to their own private practice, to a person or agency paying them, or to a person or agency in which they have a financial interest. The intent is that the SAP should make the best therapeutic decision possible, and be unable to derive direct or indirect financial benefit from their choice of referral. An exception may be made if the SAP refers the employee to a public agency; to a person or group under contract to the employer to provide drug or alcohol treatment; to the sole source of a therapeutically appropriate treatment under the employee's health insurance program; or to the sole source of a therapeutically appropriate treatment reasonably accessible to the employee.

The choices generally available to the SAP for referral would include an education program or 12-step meetings; outpatient individual or group counseling; or inpatient treatment or day-treatment. Under no circumstances may the SAP refer a covered employee to a category of care below that required clinically or defer the decision of an employee's referral to a medical service provider or the employer.

In very rare cases, the SAP may recommend that the covered employee requires no assistance at all. In such circumstances, at the carrier's discretion, the employee may be placed immediately back to covered service after successfully passing a return-to-work Federal test. The employee is still subject to follow-up testing which may last up to 60 months at the discretion of the SAP.

The result of the SAP's initial assessment should be placed in a letter to the employer. The contents of the letter are described in the Substance Abuse Professional Procedures Guidelines for Transportation Workplace Drug and Alcohol Testing Programs (June 1995; Office of the Secretary of Transportation). This document (herein referred to as SAP Guidelines) should be the ultimate

authority for SAP performance under the FRA rule.

12.5.3 ***Determine that carrier SAPs are conducting proper return to work assessments of eligible covered service employees.***

The SAP of record is responsible for monitoring the progress of the covered employee throughout the treatment plan, and is expected to be in regular contact with both the employee and the treatment, counseling, or education professionals handling the employee's case. The SAP is free to utilize other referral resources during the course of the treatment plan, or escalate or downgrade the category of care if it is in the best interests of the employee's rehabilitation. Under no circumstances can those decisions be delegated beyond the SAP of record, or be influenced by the rules of a medical service provider, a managed care organization, or an employee assistance program.

The SAP's recommendation for return to work is intended to be the primary basis for the carrier's decision whether to return an employee to covered service, but the timing of the employee's return is always at the discretion of the carrier. In some cases, the employee may even be terminated and not offered a return to covered service by that employer. In Subpart E cases (Troubled Employees), however, return to covered service cannot be unreasonably withheld if the employee has cooperated fully with the SAP's requirements

The SAP's return to work assessment must also be conducted face-to-face, and must consider whether the employee has made sufficient clinical progress to warrant return to safety-sensitive functions. Usually, completion of the first phase of treatment or counseling and some measure of aftercare is expected before a return to work assessment is scheduled. Under no circumstances may the SAP recommend an employee for return to covered service until the SAP is confident that the individual is a low risk to violate FRA drug and alcohol prohibitions.

The results of the SAP's return to work assessment should be placed in a letter to the employer. The contents of the letter are described in the SAP Guidelines.

12.6 THE FEDERAL RETURN-TO-WORK TEST AND FOLLOW-UP TESTING

12.6.1. *Determine that covered employees are not being returned to covered service until the SAP has made a formal written recommendation and the results of a Federal return-to-work test have been received by the carrier.*

Employees may not re-enter covered service until the carrier has received the SAP's recommendation, a Federal return-to-work test is performed, and the negative result has been received by the employer. The timing of the employee's return is totally at the discretion of the employer, with the exception of FRA-mandated suspensions (i.e. nine months out on a refusal, etc.) which may establish some minimum requirements for being placed out-of-service.

Employees must receive a Federal return-to-work test only if the original nexus was a violation of FRA regulations. A company reasonable cause test is not a Federal test, and entrance into a FRA voluntary referral program also does not have as its basis a violation of FRA prohibitions.

Although there is no formal limitation on the number of times an employee can be found in violation of FRA drug and alcohol regulations and be returned to covered service, FRA expects that carriers will not permit a revolving door policy. More than one violation of 219.101, 219.102, and/or 219.107 regulations (and consequent removal from covered service) would seem to be a sufficient demonstration that the employee will be an ongoing risk to rail safety. A carrier should expect that FRA will question their decision to retain such an employee in the interests of 219.104.

12.6.2 *Determine that covered employees being returned to covered service are receiving sufficient Federal follow-up tests to comply with the plan provided by the SAP.*

The SAP is responsible for providing the carrier with the number and frequency of follow-up tests to be conducted by the employer. It is the carrier's determination when to test. The carrier or its EAP may not countermand the SAP's decision on follow-up test frequency. At least six tests are required in the first 12 months, but the SAP should individualize the requirement for each employee depending on the SAP's judgment as to the employee's problem. It is the SAP's determination on whether the employee requires drug, alcohol, or both types of follow-up tests. If the returning employee is an engineer, drug and alcohol tests are mandatory.

RETURN-TO-WORK & FOLLOW-UP TESTING

Although follow-up testing may be conducted for up to 60 months, the SAP may re-assess the frequency each year and terminate follow-up testing any time after the first year. In general, two years would be an appropriate timeframe for most employees, with longer follow-up programs necessary for more difficult cases depending on the SAP's assessment of the depth of the problem.

Follow-up testing should be unannounced, and every effort must be made by the carrier to ensure that the follow-up program acts as a deterrent for the covered employee. Tests should be administered unpredictably within the working day, working week, month, and year. Employees who do not have predictable hours may be called to duty to be tested, but the employer should use this option sparingly to avoid the appearance of harassing the employee.

Follow-up tests are independent tests, and random tests or other tests may not be used in lieu of the scheduled follow-up test and vice-versa.

No Federal follow-up tests are required when the employee has graduated from a FRA voluntary referral program, although nothing prohibits the carrier from mandating a company return-to-work test and follow-ups to ensure compliance with 219.105.

Return to Covered Service Summary Checklist

I. <u>The Substance Abuse Professional (SAP)</u> [12.5]

A. *Determine that the SAPs performing the service for the carrier are fully qualified under Department of Transportation guidance.* [12.5.1]

B. *Determine that carrier SAPs are conducting proper initial assessments of covered service employees referred to them and referring employees in accordance with the SAP guidance.* [12.5.2]

C. *Determine that carrier SAPs are conducting proper return to work assessments of eligible covered service employees.* [12.5.3]

II. <u>The Federal Return-to-Work Test and Follow-Up Testing</u> [12.6]

A. *Determine that covered employees are not being returned to covered service until the SAP has made a formal written recommendation and the results of a Federal return-to-work test have been received by the carrier.* [12.6.1]

B. *Determine that covered employees being returned to covered service are receiving sufficient Federal follow-up tests to comply with the plan provided by the SAP.* [12.6.2]

13.0

IDENTIFICATION

OF

TROUBLED

EMPLOYEES

13.0 IDENTIFICATION OF TROUBLED EMPLOYEES

13.1 OVERVIEW

FRA regulations found in 49 CFR 219.401 – 219.407 (Subpart E) describe FRA requirements for the identification of covered employees impacted by drugs and/ or alcohol who have not yet been found in violation of FRA's drug and alcohol use prohibitions. FRA's intent is that carriers implement voluntary self-referral and co-worker report programs which are viable, active, and accessible to carrier covered employees. FRA's goal is the railroad will provide a realistic opportunity for covered employees with substance abuse problems to seek confidential assistance on their own (voluntary referral) and an opportunity to protect the safety of themselves and their fellow employees without endangering the livelihood of the troubled employee (co-worker report).

13.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Co-Worker
- 219.401 – Requirement for Policies
- 219.402 – [Reserved]
- 219.403 – Voluntary Referral Policy
- 219.404 – [Reserved]
- 219.405 – Co-Worker Report Policy
- 219.406 – [Reserved]
- 219.407 – Alternate Policies

13.3 INSPECTION GOAL

The goal for inspecting this element is to determine whether the carrier has made a good faith effort to develop and support voluntary referral and co-worker report programs, and/or has an alternate type of program in place which is acceptable to FRA.

13.4 RECORDS REQUIRED

The inspector should evaluate all carrier policies, published documents, and handouts relating to voluntary referral and co-worker report. Interviews shall be conducted with carrier Employee Assistance Program (EAP) or equivalent personnel and employees in the field. Data from the carrier's EAP, SAP, and other resources should be examined. Carriers should be able to segregate Federal data from data from other non-covered employees so that the carrier and FRA can easily track the utilization of the Federal programs.

13.5 THE VOLUNTARY REFERRAL PROGRAM

13.5.1 *Determine if the carrier maintains an active voluntary referral program, and supports it by encouraging participation through advertisement, handouts or postings, employee meetings, etc.*

The carrier should maintain a voluntary referral program policy which is available for FRA inspection. The policy should encompass all elements described in 219.403, including how the employee can access the program in a confidential manner; what is available to the employee in terms of a leave of absence (which must be able to extend 45 days or more); the degree to which confidentiality must be maintained by the program and by the carrier; and the mechanism for becoming eligible to return to work.

Although the rule mentions only the Substance Abuse Professional (SAP) in the assessment and return to work role, voluntary referral programs have traditionally fallen within the capable responsibility of a carrier's Employee Assistance Program (EAP). Even though an EAP service provider is not necessarily qualified as a SAP, FRA will continue to permit a qualified and experienced EAP professional to perform the responsibilities outlined in 219.403 on behalf of the carrier.

The carrier's voluntary referral program should be sufficiently well advertised that all covered employees are knowledgeable about the program and understand how to access it. The FRA rule does not require that the carrier compensate the employee while the employee is out of service or is on medical leave to attend treatment. FRA also does not require the carrier to honor the voluntary self-referral if the employee anticipated being detected by the railroad and was attempting to use the program as a safe haven.

In addition, participation in the program does not exempt the employee from disciplinary action or dismissal for rule violations or criminal offenses determined independently from the referral. The carrier may choose in its policy to limit access to the program to those who have not previously used it or have never previously been identified under the carrier's co-worker report policy.

13.5.2 ***Determine that the carrier is implementing the voluntary referral program consistent with the intent of the regulations.***

Access to the program should be confidential, and referrals should be acceptable from the employee themselves, a fellow employee, or a union representative. The carrier is also permitted to expand this list to include referrals from other sources (i.e., supervisory employees). If supervisors are going to be allowed as part of the referral program, the carrier's written policy must clearly explain how this will work and yet also support other mandatory programs such as reasonable suspicion testing. Mandatory reasonable suspicion must always take precedence over a voluntary referral for a supervisor.

A contact mechanism (toll-free telephone number, etc.) should be well publicized on the property. The confidential contact offered to the employee may only be fulfilling a role equivalent to an EAP, SAP, or other employee assistance effort, and may not be a supervisor or management official unless they are part of such a program.

If necessary based on the extent of the employee's problem, the carrier must grant the employee a leave of absence of at least 45 days to allow completion of primary counseling or treatment and to stabilize the drug and/or alcohol problem. If properly complying with program requirements, the employee's employment relationship with the carrier must remain intact while they are enrolled and making satisfactory progress.

If permitted by the carrier's policy, the employee may have their confidentiality waived if they refuse to cooperate with the treatment plan, or they continue their alcohol and/or drug misconduct.

To return to work in covered service, the employee must successfully complete at least the initial phase of a counseling or treatment program, if applicable, and be recommended for return to work by the EAP or the SAP. The ability of the employee to return to full covered duty may not be unreasonably withheld by the carrier, but the railroad is permitted to require a return-to-service medical

exam as a condition of reinstatement. Although this program is a Federal requirement, Federal return-to-work and follow-up tests are not necessary because no violation of FRA regulations has been charged. Nothing limits however, the company requiring such testing under its own authority.

13.6 THE CO-WORKER REFERRAL PROGRAM

13.6.1 *Determine if the carrier maintains an active co-worker report program, and supports it by encouraging participation through advertisement, handouts or postings, employee meetings, etc.*

The carrier should maintain a co-worker report policy which is available for FRA inspection. The policy should encompass all of the elements described in 219.405, including the criteria which co-workers should use to access the program; the mechanism to confidentially report the violation of 219.101 or 219.102 to a supervising employee; the procedure by which the allegation is to be properly investigated and affirmed as a violation by a railroad representative; the rights of the employee when confronted with the violation; the criteria for program eligibility (including waiver of the rule charge violation and the requirement to contact the SAP within a designated timeframe); the mechanism for becoming eligible to return to work (including the role of the SAP); and follow-up testing requirements.

The carrier's written policy must clearly explain what the role of the supervisor is to be, and how action under this program can be distinguished from other mandatory programs such as reasonable suspicion. Ordinarily, if the supervisor uncovers the 219.101 or 219.102 violation only because of the intercession of the co-worker, the employee should be eligible for the co-worker report program. If the supervisor would have almost instantaneously discovered the employee's violation on their own, a co-worker cannot attempt to use the program as a means of protecting the employee or avoiding disciplinary action for that employee.

The carrier's co-worker report program should be well advertised in a manner which ensures that all covered employees are knowledgeable about the program's existence and understand how to access it.

FRA guidance on employee compensation while out of service applies equally for co-worker report as it did for voluntary referral. Enrollment in a treatment program because of a co-worker report is usually a one-time opportunity, and should not generally be allowed for a second offense.

13.6.2 ***Determine that the carrier is implementing the co-worker report program consistent with the intent of the regulations.***

Co-workers who wish to come forward to report a fellow employee must be made fully knowledgeable of how to properly contact supervision. They must be made aware before they identify the rule violation that disciplinary action can only be waived if the identified covered service employee accepts help in lieu of discipline. If properly complying with the program, however, the identified employee's employment relationship with the carrier must remain intact.

Confidentiality for the troubled employee is not necessarily granted under the co-worker report program. However, if granted by the carrier in its policy, confidentiality can be waived if the employee fails to cooperate with the program or engages in continued drug and/or alcohol use. The criteria for leave of absence and return to work described previously under the voluntary referral section of this Manual similarly applies here.

To return to work in covered service, the employee must successfully complete at least the initial phase of a counseling or treatment program, if applicable, and be recommended for return to work by the SAP. The ability of the employee to return to full covered duty may not be unreasonably withheld by the carrier, but the railroad is permitted to require a return-to-service medical exam as a condition of reinstatement.

With co-worker report, a Federal return-to-work test is required. In addition, there should be greater emphasis on monitoring the identified employee with a Federal follow-up drug and/or alcohol testing program. The SAP should determine the number and frequency of follow-up tests, with the employer determining the dates. Return to work and follow-up tests are to be Federal tests even if no violation of FRA regulations has been formally charged.

13.7 ALTERNATE PROGRAMS

The regulation permits the carrier to implement an alternative program to the voluntary referral and/or co-worker report programs required by the regulation. The alternate programs may be limited to any group of covered carrier employees, but anyone not participating in the alternate program must be covered by a voluntary referral and co-worker report program identical in scope to that previously described. Any alternative program must have the written concurrence of the union(s) representing the group of affected employees and be filed with the FRA. Any changes to the alternate program (including revocation) must be filed with FRA 30 days in advance of implementation. The alternative program, to be acceptable to FRA, must be similarly protective of both the carrier and the troubled employee as are the voluntary referral and co-worker report programs. It may not be used as a mechanism to avoid or circumvent FRA's intent with regard to this portion of the rule.

Troubled Employees Summary Checklist

I. The Voluntary Referral Program [13.5]

A. *Determine if the carrier maintains an active voluntary referral program, and supports it by encouraging participation through advertisement, handouts or posting, employee meetings, etc.* [13.5.1]

B. *Determine that the carrier is implementing the voluntary referral program consistent with the intent of the regulations.* [13.5.2]

II. The Co-Worker Referral Program [13.6]

A. *Determine if the carrier maintains an active co-worker report program, and supports it by encouraging participation through advertisement, handouts or postings, employee meetings, etc.* [13.6.1]

B. *Determine that the carrier is implementing the co-worker report program consistent with the intent of the regulations.* [13.6.2]

14.0

RECORDS

AND

CONFIDENTIALITY

14.0 RECORDS AND CONFIDENTIALITY

14.1 OVERVIEW

FRA regulations found in 49 CFR 219.901 – 219.905 (Subpart J) summarize carrier recordkeeping requirements. FRA regulations found in 49 CFR 219.711 and Department of Transportation regulations found in 40.35, 40.81, and 40.109 summarize confidentiality requirements for test results. Other confidentiality elements are described throughout the Rule text and in guidance documents for the Medical Review Officer (MRO) and the Substance Abuse Professional (SAP). FRA's intent is to establish the minimum carrier recordkeeping and confidentiality requirements of the Rule. FRA's goal is that the carrier will maintain sufficient records and recordkeeping systems which allow it to properly document full compliance with Part 219 elements. In most cases, acceptable documentation for an audit may need to exceed that described in Subpart J. The carrier must also ensure that all of its records and internal and external communications are fully protective of the right to privacy of its employees.

14.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 219.901 – Retention of Breath Alcohol Testing Records
- 219.902 – [Reserved]
- 219.903 – Retention of Urine Drug Testing Records
- 219.904 – [Reserved]
- 219.905 – Access to Facilities and Records
- 219.711 – Confidentiality of Test Results
- 40.35 – Protection of Employee Records (Drug Testing)
- 40.81 – Availability and Disclosure of Alcohol Testing Information About Individual Employees (Alcohol Testing)
- 40.109 – Availability and Disclosure of Alcohol Testing Information About Individual Employees (Non-Evidential Alcohol Screening Tests)

RECORDS AND CONFIDENTIALITY

14.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier retains records for as long as required in 219.901 and 219.903. It must also be determined that the carrier maintains appropriate confidentiality on applicable records and test results, limiting internal access to a strict need-to-know basis and external access based on the limitations imposed by the FRA and DOT rules.

14.4 RECORDS REQUIRED

The inspector should examine the records outlined in 219.901 and 219.903 to determine whether they are being retained for the proper duration. The inspector should also examine how the carrier maintains confidentiality. Employees and supervisors should be interviewed and documents which are associated with the release of information outside the carrier should be reviewed.

14.5 RECORDKEEPING

14.5.1 *Determine that the carrier retains drug and alcohol records described in 219.901 and 219.903 for the proper duration.*

The carrier is required to retain the following drug and alcohol records in a secure location for five years:

- Records detailing verified drug positive tests and alcohol positives of 0.02% or above (including custody and control forms)
- Records on drug and alcohol test refusals
- Records on Evidential-Level Breath Testing (EBT) instrumentation calibrations (including for devices maintained by contract collectors)
- Records on employee SAP referrals, return-to-duty recommendations, return to work tests, and follow-up tests
- A summary of each covered employee's drug and alcohol testing history.
- Documentation on the annual MIS submission

RECORDS AND CONFIDENTIALITY

The carrier is required to retain the following drug and alcohol records in a secure location for two years:

- Records on the random selection process, including but not limited to, computer code, pool entries, selections, and reasons for no-tests
- Records on all reasonable suspicion and Federal reasonable cause determinations
- Records on all shy bladder and shy lung determinations
- Records documenting reasonable suspicion/Federal reasonable cause training for supervisors, including training content

The carrier is required to retain the following drug and alcohol records in a secure location for one year:

- Records detailing negative drug and alcohol tests (including custody and control forms)

In some cases, records may be maintained by a contract service provider as long as they are properly secured, but must be retrievable with three days notice.

14.5.2 ***Determine that the carrier maintains records in a secure location and appropriately limits access.***

Carriers must ensure that records maintained in compliance with this rule are properly secured and that carrier personnel without a direct need-to-know are not granted access.

14.6 CONFIDENTIALITY

14.6.1 ***Determine that the carrier maintains proper confidentiality on all drug and alcohol testing information, limiting internal communications to a strict need-to-know basis.***

Positive and negative test results may not be communicated by the carrier to its personnel except on a strict need-to-know basis. In the case of relieving a verified positive employee from covered service, the carrier or its representatives may not

themselves disclose the reason to any management employee, supervisor, or worker unless it is absolutely necessary to perform the required removal.

14.6.2 ***Determine that the carrier does not release test information on applicants and covered employees to outsiders without a written release of information from the donor, or as provided for by the rule or other Federal authority.***

Requests for specific test information on applicants and covered employees may not ordinarily be released to an outside person or agency without a written release from the donor that specifies the type of information to be released and the time period the release applies. Exceptions to this rule include release of information required by law (a bona-fide subpoena or other legal instrument); as necessary for the carrier to defend itself in a legal or administrative employment action taken by the applicant or employee; to the NTSB as part of an accident investigation; to the FRA; or to other Federal agencies as directed by the rule.

Records and Confidentiality Summary Checklist

I. Recordkeeping [14.5]

A. *Determine that the carrier retains drug and alcohol records described in 219.901 and 219.903 for the proper duration.* [14.5.1]

B. *Determine that the carrier maintains records in a secure location and appropriately limits access.* [14.5.2]

II. Confidentiality [14.6]

A. *Determine that the carrier maintains proper confidentiality on all drug and alcohol testing information, limiting internal communications to a strict need-to-know basis.* [14.6.1]

B. *Determine that the carrier does not release test information on applicants and covered employees to outsiders without a written release of information from the donor, or as provided for by the rule or other Federal authority.* [14.6.2]

TAB 1

URINE SPECIMEN COLLECTION AND REPORT FORMS

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO.

A- 1003489067

Quest Diagnostics

Quest Diagnostics Incorporated
7470 Mission Valley Rd. • San Diego, CA 92108-4406 • 800•647•2827 / 619•686•3200

OMB #9999-0023
EXP. DT 6/30/97

LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No.

ABC Railroad
4567 South Maple Avenue
Des Plaines, IL 60018

B. MRO Name and Address

James Bernstein, MD
7890 Elvis Presley Blvd
Memphis, TN 38182

C. Donor SSN or Employee I.D. No. 548-68-2183

D. Reason for Test: ☐ Pre-employment ☒ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☒ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☒ Yes, 90° - 100°F/32°C - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

▶ STEP 4: SEE BELOW

STEP 5: TO BE COMPLETED BY COLLECTOR - Return to Copy 1

COLLECTION SITE LOCATION:

GREAT LAKES OCCUPATIONAL HLTH (847) 567-8910
Collection Facility / Collector's Business Phone No.

123 BIG LAKE BLVD / DES PLAINES / IL / 60027
Address / City / State / Zip

SPLIT SPECIMEN COLLECTION ☒ YES ☐ NO

REMARKS:

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

JAMES L. JOHN (PRINT) Collector's Name (First, MI, Last) | X James L. John Signature of Collector | 10/8/99 Date (Mo./Day/Yr.) | 345 Time (AM) PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
10/8/99	DONOR - NO SIGNATURE	Signature: James L. John Name: JAMES L. JOHN	PROVIDE SPECIMEN FOR TESTING
10/8/99	Signature: James L. John Name: JAMES L. JOHN	Signature: BOB'S COURIER Name: SERVICE	SEND SPECIMEN TO LAB
/ /	Signature: Name:	Signature: Name:	
/ /	Signature: Name:	Signature: Name:	

▶ STEP 4: TO BE COMPLETED BY DONOR

Daytime Phone No. (847) 654-3210 Evening Phone No. (847) 321-0667 Date of Birth 06 / 09 / 50 (Mo. / Day / Yr.)

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each bottle is correct.

KENNETH SWART (PRINT) Donor's Name (First, MI, Last) | X Kenneth Swart Signature of Donor | 10/8/99 Date (Mo./Day/Yr.)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).-DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☒ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled REMARKS _____

LINDA EVENS, MD (PRINT) Medical Review Officer's Name (First, MI, Last) | Linda Evens, MD Signature of Medical Review Officer | 10/10/99 Date (Mo./Day/Yr.)

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO.

A-1003489067

Quest Diagnostics

Quest Diagnostics Incorporated
7470 Mission Valley Rd. • San Diego, CA 92108-4406 • 800-647-2827 / 619-686-3200

OMB#9999-0023
EXP. DT. 6/30/97

LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No.

ABC Railroad
4567 South Maple Avenue
Des Plaines, IL 60018

B. MRO Name and Address

James Bernstein, MD
7890 Elvis Presley Blvd
Memphis, TN 38182

C. Donor SSN or Employee I.D. No. 548-68-2183

D. Reason for Test: ☐ Pre-employment ☒ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☒ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☒ Yes, 90° - 100°F/32°C - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: TO BE COMPLETED BY DONOR - Go to copy 4 (pink page); STEP 4

STEP 5: TO BE COMPLETED BY COLLECTOR

COLLECTION SITE LOCATION:

GREAT LAKES OCCUPATIONAL HLTH (847) 567-8910
Collection Facility / Collector's Business Phone No.

123 BIG LAKE BLVD / DES PLAINES / IL / 60027
Address / City / State / Zip

SPLIT SPECIMEN COLLECTION ☒ YES ☐ NO

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

JAMES L. JOHN (PRINT) Collector's Name (First, MI, Last) | X James L. John Signature of Collector | 10/8/99 Date (Mo./Day/Yr.) | 345 AM (PM) Time

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
10/8/99	DONOR - NO SIGNATURE	Signature: James L. John Name: JAMES L. JOHN	PROVIDE SPECIMEN FOR TESTING
10/8/99	Signature: James L. John Name: JAMES L. JOHN	Signature: BOB'S COURIER Name: SERVICE	SEND SPECIMEN TO LAB
/ /	Signature: Name: COURIER	Signature: Maria Main Name: MARIA MAIN	Rec'd Placed in secure storage
/ /	Signature: Name:	Signature: Name:	

STEP 7: TO BE COMPLETED BY THE LABORATORY - Specimen Bottle Seal(s) Intact: ☐ YES ☐ NO, Explain in Remarks Below.

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE INITIAL TEST AND CONFIRMATORY TEST CUTOFF LEVELS ESTABLISHED BY THE HHS *MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS*

☒ NEGATIVE ☐ POSITIVE, for the following ☐ CANNABINOIDS as Carboxy - THC ☐ COCAINE METABOLITES as Benzoylecgonine ☐ PHENCYCLIDINE

☐ OPIATES: ☐ codeine ☐ morphine

☐ AMPHETAMINES: ☐ amphetamine ☐ methamphetamine

☐ TEST NOT PERFORMED ☐ OTHER _____

REMARKS _____

TEST LAB (if different from above) _____ NAME _____ ADDRESS _____ ( ) PHONE NO.

I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth are for that specimen.

JOSEPH PLANDER (PRINT) Certifying Scientist's Name (First, MI, Last) | Joseph Plander Signature of Certifying Scientist | 10/9/99 Date (Mo./Day/Yr.)

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☒ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled REMARKS _____

LINO EVENS, MD (PRINT) Medical Review Officer's Name (First, MI, Last) | Linda Evens, MD Signature of Medical Review Officer | 10/10/99 Date (Mo./Day/Yr.)

Quest Diagnostics

7470 Mission Valley Road
San Diego, CA 92108
1 (800) 647-2827 Client Services
1 (800) 446-4728

ABC Railroad
4567 South Maple
Des Plaines, IL 60018

Patient Name/Specimen I.D.

Patient I.D./SSN 1003489067

548-68-2183

Requesting Physician/Contact Name

Request Type: Random

Collection Site:

Remarks:

Accession No.

Other I.D. S100897634

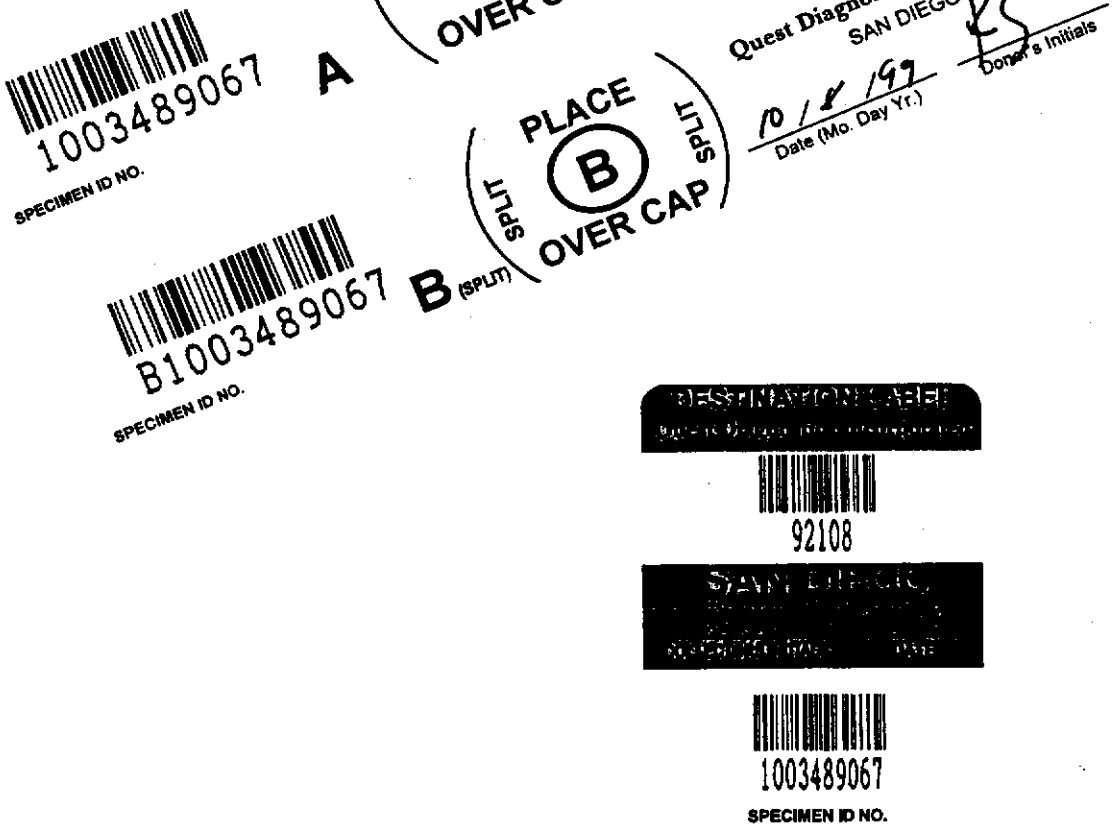
Specimen Type

	Date	Time
Collected:	10-08-99	
Received:	10-09-99	
Reported:	10-10-99	
Status:	FINAL REPORT	

ORENSIC PANEL 157

Test Name	Results	Initial Test Level (ng/mL)	Confirm Test Level (ng/mL)
AMPHETAMINES	Negative	1000	500
COCAINE METABOLITES	Negative	300	150
PHENCYCLIDINE (PCP)	Negative	25	25
CANNABINOIDS	Negative	50	15
OPIATES/METABOLITES	Negative	2000	2000

Initial screen for all drugs performed by Enzyme Immunoassay.
This specimen has been evaluated for adulteration.


1003489067
SPECIMEN ID NO.
A
PLACE
A
OVER CAP
Quest Diagnostics Incorporated
SAN DIEGO
10 / 8 / 99
Date (Mo. Day Yr.)
Donor's Initials
B1003489067
SPECIMEN ID NO.
B (SPLIT)
SPLIT
PLACE
B
OVER CAP
SPLIT
Quest Diagnostics Incorporated
SAN DIEGO
10 / 8 / 99
Date (Mo. Day Yr.)
Donor's Initials
92108
1003489067
SPECIMEN ID NO.

TAB 2

BREATH SPECIMEN COLLECTION AND REPORT FORMS

U.S. Department of Transportation (DOT)
Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

▶ STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

A. Employee Name DON EDGELL
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. 321-43-6964

C. Employer Name, Address, & Telephone No.
ABC RAILROAD
4567 SOUTH MAPLE AVENUE
DES PLAINES, IL
847 789-0123
Telephone Number

D. Reason for Test: ☐ Pre-employment ☒ Random ☐ Post-accident
☐ Reasonable Suspicion/Cause ☐ Return to Duty ☐ Follow-up

▶ STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

Don Edgell
Signature of Employee

Date 9, 21, 99
Month Day Year

▶ STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete **only if** the testing device is not designed to **print** the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time (AM / PM)	Result

Confirmation test: Confirmation test results **MUST** be affixed to the back of each copy of this form or printed on the space to the right of each front copy.

Remarks:

(PRINT) Breath Alcohol Technician's Name (First, M.I., Last)

Signature of Breath Alcohol Technician

Date 9, 21, 99
Month Day Year

▶ STEP 4: TO BE COMPLETED BY EMPLOYEE

I certify that I have submitted to the breath alcohol test the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are 0.02 or greater.

Don Edgell
Signature of Employee

Date 9, 21, 99
Month Day Year

OMB No. 2105-0529
Exp. Date: 2/28/97
371-FS-C3

COPY 1-ORIGINAL-FORWARD TO THE EMPLOYER

AFFIX SCRE EVIDENCE ERE

RBT IV# 012868
DATE 09-21-99
TEST NO. 0777
ID#
560372740
AS IV# 006088
SCREENING
G/210L TIME
------ ----
.000 AUTO 15:06

USE T. TAPE

AFFIX CONFIRMATION TEST RESULTS HERE

USE TAMPER-EVIDENT TAPE

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 1 - ORIGINAL - FORWARD TO THE EMPLOYER

OMB No. 2105-0529
Exp. Date: 2/28/97

TAB 3

MANDATORY POST-ACCIDENT COLLECTION AND REPORT FORMS

U.S. Department of Transportation
Federal Railroad Administration

ACCIDENT INFORMATION REQUIRED FOR POST-ACCIDENT TOXICOLOGICAL TESTING (49 CFR PART 219)

NOTE: This form must be completed by the Railroad Representative present at the collection facility.

1. Name of Reporting Railroad	2. Name(s) of Other Railroads Involved in Accident
ABC RAILROAD	N/A
3. Date of Accident (month /day/year)	**4. Time of Accident**
11/9/99	4 Hr : 15 Min ☒ AM ☐ PM
5. Locations of Accident (City and State)	**6. Nearest Railroad Station**
MILEPOST 153	DES PLAINES, IL

7. Event which Qualifies Accident for Mandatory Post-Accident Testing (one must be checked)

NOTE: All accident events (not incidents) must meet the railroad property damage reporting threshold.

MAJOR TRAIN ACCIDENT:	___	Fatality
	X	$1,000,000 damage or more (to railroad property)
	___	Release of hazardous material (and evacuation)
	___	Release of hazardous material (and reportable injury from product)
IMPACT ACCIDENT:	___	Reportable injury
	___	Damage of $150,000 or more (to railroad property)
PASSENGER TRAIN ACCIDENT:	___	Reportable injury to any person in the accident
TRAIN INCIDENT:	___	Fatality to on-duty railroad employee

8. Name and Address of Collection Facility	9. Telephone Number of Collection Facility
GREAT LAKES OCCUPATIONAL HEALTH 123 BIG LAKE BLVD. DES PLAINES, IL 60027	(847) 567-8910

10. Employee(s) Whose Samples are Contained in this Shipping Box.

NOTE: A sample set identification number is pre-printed on FRA Form 6180.74 and differs for each person.

NAME OF EMPLOYEE	JOB TITLE (engineer, conductor, etc.)	TRAIN DESIGNATION	SAMPLE SET IDENTIFICATION NUMBER
KEN SWART	ENGINEER	XYZ123	112603
DON EDGELL	CONDUCTER	XYZ123	112605
MARY SHATINSKY	ENGINEER TRAINEE	XYZ123	112604

11. Name of Medical Review Officer	12. Address of Medical Review Officer
JIM BERNSTEIN, MD 7890 ELVIS PRESLEY ROAD MEMPHIS TN 38182	Telephone: (901) 234-5678
13. Name of Railroad Representative	**14. Address of Railroad Representative**
WOODIE WOODWARD 4567 SOUTH MAPLE AVENUE DES PLAINES, IL 60018	Telephone: (847) 789-0123

15. Signature of Railroad Representative	16. Date (month/day/year)	17. Was a breath alcohol test conducted pursuant to the above accident under FRA Authority?	
Woodie Woodward	11/9/99		☒ Yes ___ No

FEDERAL RAILROAD ADMINISTRATION
POST-ACCIDENT TESTING BLOOD/URINE CUSTODY AND CONTROL FORM (49 CFR 219)

NOTE: This form must be completed in accordance with instructions provided by the Railroad representative. Separate instructions are available for the employee and the collectors. If more than one collector provides services, each must direct special attention to properly documenting the chain of custody for the blood and urine specimens, as applicable.

Employee Identification Number or Social Security Number	Sample Set Identification Number (*Pre-printed*)
548-68-2183	112603

STEP 1. COMPLETED BY EMPLOYEE (DONOR) PROVIDING SPECIMENS

Name *Print (last, first, mi)*	Name of Employing Railroad
SWART, KENNETH R.	ABC RAILROAD

Home Address	Name of Home terminal
6543 COLUMBIA AVENUE DES PLAINES IL 60014	DES PLAINES

STEP 2. COMPLETED BY COLLECTOR OF BLOOD SPECIMEN

Name of Collector *Print (last, first, mi)*	Collection Date / Time	Remarks:
LEE, SARA J.	11/9/99 / 0735	

I certify the blood specimen was presented to me by the person named in Step 1. The specimen (in two blood tubes) bears the sample set identification number as printed above and was collected, labeled, and sealed according to the Federal Railroad Administration's instructions provided to me.

I HAVE COMPLETED THE REQUIRED ENTRY IN STEP 5 BELOW, AS EXPLAINED IN THE INSTRUCTIONS GIVEN TO ME.

Sara J. Lee MT
Signature of Collector

STEP 3. COMPLETED BY COLLECTOR OF URINE SPECIMEN

Name of Collector *Print (last, first, mi)*	Collection Date / Time	Remarks:
CROCKER, BETTY L.	11/9/99 / 0750	

Temperature of Specimen was read within 4 minutes	Temperature was within range of 32°–38°C/90°–100°F	If not, actual temperature was
☒ YES ☐ NO	☒ YES ☐ NO	_____ °

I certify the urine specimen was presented to me by the person named in Step 1. The specimen (in two bottles) bears the sample set identification number as printed above and was collected, labeled, and sealed according to the Federal Railroad Administration's instructions provided to me.

I HAVE COMPLETED THE REQUIRED ENTRY IN STEP 5 BELOW, AS EXPLAINED IN THE INSTRUCTIONS GIVEN TO ME.

Betty L. Crocker
Signature of Collector

STEP 4. COMPLETED BY EMPLOYEE

I certify the information I have given in Step 1 is correct and that I provided the specimens described in Steps 2 and 3; that each specimen is in a container which have the above sample set identification numbers recorded on the tamper-evident seals; that I have not adulterated the urine specimen in any manner, that each container has a tamper-evident seal that was applied by the collector in my presence, and I have placed my initials on each label. (SIGN AFTER ALL SPECIMENS ARE SEALED.)

EXAMPLE OF MY INITIALS: KS

Kenneth R. Swart
Signature of Employee

STEP 5. COMPLETED IN SEQUENCE BY COLLECTORS AND OTHERS TAKING POSSESSION OF SPECIMENS *(Including Laboratory)*

DATE MO. DAY YR.	SPECIMEN RELEASED BY	TYPE OF FLUID(S) BLOOD	TYPE OF FLUID(S) URINE	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
11/9/99	DONOR- NO SIGNATURE	2		Signature: Sara J Lee MT Name: SARA J. LEE	PROVIDE SPECIMEN FOR TESTING
11/9/99	Signature: Sara J Lee MT Name: SARA J. LEE	2		Signature: Betty L. Crocker Name: BETTY L. CROCKER	TRANSFER SPECIMENS TO SECOND COLLECTOR
11/9/99	Signature: DONOR Name:		2	Signature: Betty L. Crocker Name: BETTY L. CROCKER	PROVIDE SPECIMEN FOR TESTING
11/9/99	Signature: Betty L. Crocker Name: BETTY L. CROCKER	2	2	Signature: JIM'S OVERNIGHT Name: COURIER SERVICE	TRANSFER SPECIMENS TO LAB

STEP 6. COMPLETED BY MEDICAL FACILITY/PHYSICIAN

Describe any medication, solution, transfusion, anesthetic, or other treatment the employee received after the accident that might affect toxicological analyses.

None

Was a breath alcohol test conducted on the donor above, pursuant to this accident, using FRA authority? ☒ Yes ☐ No

Northwest Drug Testing, NWT Inc.
1141 East 3900 South Salt Lake City, UT 84124 800-322-3361

FEDERAL RAILROAD ADMINISTRATION POST-ACCIDENT FORENSIC TOXICOLOGY RESULT REPORT

REFERENCE INFORMATION

RAILROAD:	ABC RAILROAD		
ACCIDENT:	Des Plaines, IL	11/09/99	4:15 am
FRA CASE:	987		
EMPLOYEE:	Kenneth R. Swart		
SPECIMEN SET ID NO:	112603		

SPECIMEN(S) TESTED

URINE:	FR8042
BLOOD:	FR8042

LABORATORY TESTING INFORMATION

Drug	Urine	Blood
Cannabinoids	NEG	*
Cocaine	NEG	*
Opiates	NEG	*
Amphetamine	NEG	*
Methamphetamine	NEG	*
Phencyclidine	NEG	*
Barbiturates	NEG	*
Benzodiazepines	NEG	*
Ethyl Alcohol	*	NEG

* Testing not required; see attached summary

TESTING PERFORMANCE EXPLANATION

Testing of specimens was in accordance with the FRA Post-Accident Testing Program. Additional descriptive information of testing procedures are summarized on the attachment "Summary of Analyses Performed on Specimens for Toxicology under FRA Post-Accident Testing Program" (Revised 2/02/99), which is an integral part of this report.

SPECIMEN DISPOSITION

Negative specimens will be retained at NWT Inc, for not less than six months from the report date. Positive specimens will be retained for not less than two years.

RESULTS

NO DRUGS OR ALCOHOL WERE IDENTIFIED

CERTIFICATION

I certify that I am a laboratory certifying official at NWT Inc, and the results identified above were correctly determined in accordance with the FRA Post-Accident Testing Program.

David J. Kuntz, Ph.D., Laboratory Director

11-11-99
Report Date

SUMMARY OF ANALYSES PERFORMED ON SPECIMENS FOR TOXICOLOGY UNDER FRA POST-ACCIDENT TESTING PROGRAM

Revised 2/02/99

The following summarizes the procedures for analysis of blood and urine specimens submitted under the FRA Post-Accident Program.

Urine Integrity Test: Urine is tested for pH, specific gravity, and creatinine. If the pH or temperature is out or range, the specific gravity is less than 1.003, the creatinine is less than 20 mg/dL, or the sample appears adulterated, both the urine and the blood specimens may be tested for drugs.

Analysis of Drugs/Initial Testing: Initial testing is performed on urine by KIMS (kinetic interaction of microparticles in solution), or blood, if urine is unavailable or unsuitable, by RIA (radioimmunoassay) for the drug groups shown. If the tests are negative (that is, the results are below the cut-off), routinely no further analyses are performed.

	Cutoffs (ng/mL)[b]	
Drug or Metabolite[a]	**Urine**	**Blood**
Cannabinoids	20	10
Cocaine	300	20
Opiates	300	50
Amphetamine	300	50
Methamphetamine	300	50
Phencyclidine	25	2.5
Barbiturates	200	100
Benzodiazepines	100	50

Analysis of Drugs/Confirmation: If the initial test is presumptively positive, the urine and/or the blood specimens are analyzed using gas chromatography/mass spectrometry (GC/MS). Normally, blood analysis is not required if urine results are negative. Except as noted, only positive confirmed findings at or above the cutoff are reported; they are expressed as quantitative results based on the confirmatory analysis.

		Confirmation Cutoffs (ng/mL)[b]	
Specific Drug or Metabolite		**Urine**	**Blood**
Cannabinoids			
	Delta-9-tetrahydrocannabinol (THC)[c]	N/A	1
	THCA (a metabolite of THC)	15	5
Cocaine			
	Cocaine	50	10
	Benzoylecgonine (a metabolite of cocaine)	150	10
Opiates			
	Morphine (total)	300	N/A
	Morphine (unconjugated)	N/A	20
	Codeine (total)	300	N/A
	Codeine (unconjugated)	N/A	20
	6-Monoacetylmorphine (6-MAM)	LOQ[d]	LOQ[d]
Phencyclidine		25	2.5
Amphetamines			
	Amphetamine	100[e]	20
	Methamphetamine	100[e]	20

		Confirmation Cutoffs (ng/mL)[b]	
Specific Drug or Metabolite (cont.)		**Urine**	**Blood**
Barbiturates			
	Pentobarbital	200	100
	Secobarbital	200	100
	Amobarbital	200	100
	Butalbital	200	100
	Phenobarbital	1000	1000
Benzodiazepines			
	*Nordiazepam	LOQ	20
	*Oxazepam	LOQ	20
	*Temazepam	LOQ	20
	*N-Desalkylflurazepam	LOQ	20
	*alpha-Hydroxyalprazolam	LOQ	N/A
	*alpha-Hydroxytriazolam	LOQ	N/A
	Diazepam	N/A	20
	Flurazepam	N/A	20
	Chlordiazepoxide	N/A	20
	Alprazolam	N/A	10
	Triazolam	N/A	10

**Urine benzodiazepine concentrations are reported if above the LOQ and only if the blood concentrations are above the cutoff. If a blood specimen is not received and the urine benzodiazepine concentration is greater than the LOQ, then the urine specimen may be reported.*

Note: If a drug included in a drug group is detected below the cutoff and another drug in that group is present above the cutoff, then the first drug may be reported.

Analysis for Alcohol: The blood specimen (or urine if blood is unavailable) is analyzed for ethyl alcohol by gas chromatography (GC). If the blood specimen is positive, the analysis is repeated using a separate portion of the specimen and the urine is also analyzed by gas chromatography. In fatalities, vitreous (if available) is also analyzed.

Substance	**Initial Test Cutoff (g/100 mL)**	**Confirmation Cutoff (g/100 mL)**
Ethyl Alcohol	0.01	0.01

Analysis in the Case of a Fatality: If urine or blood is not available, or as directed by the FRA, other body fluids and/or tissue specimen(s) may be analyzed.

Special Assays: On direction from the FRA, additional testing for controlled substances and/or their metabolites may be conducted. If such tests are performed, they are specifically described on each individual report.

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[a] *Metabolites and/or analogs of these compounds may also be detected.*

[b] *These cutoffs are subject to periodic review and update.*

[c] *THC is the active constituent of marijuana or hashish preparations.*

[d] *LOQ: Limit of quantitation.*

[e] *A confirmed urine positive for amphetamine or methamphetamine will result in a d&l isomer analysis and is reported as the % of each isomer present.*

End of Manual